

US3222061 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:01:53

All time stamps listed in this document are displayed in GMT

US3222061

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 15:09:11

Generated On: 11 Aug 2021 22:01:53

[Participant ID](#)

US3222061

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

US3222061

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3222061

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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

US3222061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3222061

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Were any significant conditions reported?

Yes ☒

No ☐

US3222061

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	COPD- CHRONIC PLUMONARY DISEASE
Start date (dd MMM yyyy)	01 JAN 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3222061

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	EMPHYSEMA
Start date (dd MMM yyyy)	01 JAN 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222061

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	01 JAN 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222061

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	LUNG CANCER
Start date (dd MMM yyyy)	01 JAN 2015
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3222061

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JAN 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)	_____

US3222061

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Condition	ALLERGIES - SEASONAL
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3222061

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:25
Height (xxx.x)	147.3 cm
Weight (xxx.x)	58.9 kg
BMI (xxx.x)	27.14625 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222061

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3222061

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (*dd MMM yyyy*) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____
Date of last menstruation unknown True

US3222061

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3222061

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

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

What was the participant's randomization number? 185405

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 ☒

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Height	ND - Not Done
Weight	ND - Not Done

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:25
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 11:55
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3222061

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 11:18

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

US3222061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

10:53 (24 HR)

Collection date and time (derived)

10 AUG 2020 10:53

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:54	10 AUG 2020 10:54
Nasopharyngeal Swab 2	No		

US3222061

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 11:47

PC Open Date & Time

10 AUG 2020 11:38

PC Close Date & Time

10 AUG 2020 14:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 15:45

PC Open Date & Time

10 AUG 2020 15:03

PC Close Date & Time

11 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	11 AUG 2020 14:20
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:04

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 13:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 16:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 08:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 11:47

PC Open Date & Time

10 AUG 2020 11:38

PC Close Date & Time

10 AUG 2020 14:08

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 15:45

PC Open Date & Time

10 AUG 2020 15:03

PC Close Date & Time

11 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 14:20

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:05

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 13:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 16:42

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

16 AUG 2020 08:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 11:48
PC Open Date & Time	10 AUG 2020 11:38
PC Close Date & Time	10 AUG 2020 14:08

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:46
PC Open Date & Time	10 AUG 2020 15:03
PC Close Date & Time	11 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

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 ☒

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 1645

EAB) (1725)

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:06
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1645

EAB) (1725)

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

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 ☒

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 16:43
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 1645

EAB) (1725)

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 08:32
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 1645

EAB) (1725)

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:27
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3222061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:10:43

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 SEP 2020
Time of assessment (00:00-23:59)	13:35 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 13:35
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
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="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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	

US3222061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

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

PATIENT HAS BEEN DIAGNOSED WITH BREAST CANCER AND HAS UPCOMING TREATMENT. DOSING WITHHELD, BUT PATIENT WILL CONTINUE WITH FOLLOW-UPS.

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? _____

US3222061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

14:38 (24 HR)

Collection date and time (derived)

14 SEP 2020 14:38

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	14 SEP 2020 14:42
Nasopharyngeal Swab 2	No		

US3222061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Were vital signs assessed? Yes ☐
No ☒

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 ☐
Axillary ☐
Other ☐

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 _____

Height (derived) _____

Weight (derived) _____

US3222061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

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.

US3222061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

12:30 (24 HR)

Collection date and time (derived)

12 OCT 2020 12:30

US3222061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:10:45

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 04:45:21
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

24 OCT 2020 08:52:42

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 08:19:38
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 08:12:17
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 09:11:58

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 09:07:19
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 08:29:34
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 08:10:51
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 13:02:18

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 09:10:14

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 09:46:48

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 22:14:03

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 09:51:33

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 19:06:54
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 10:07:27

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 08:41:41
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 08:12:02
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 07:50:26
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 01:16:23

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 14:19:20

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 08:29:55

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 07:29:11
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 07:25:55

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:34:47

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:42:40

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 14:17:13

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 12:00:32

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 07:23:03

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 <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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Patient Cloud Open Date & Time	11 AUG 2021 00:01
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Patient Cloud Close Date & Time	15 AUG 2021 23:59
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US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 446

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

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

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

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

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

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

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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°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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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°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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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°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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

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07 AUG 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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°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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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 ☐

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3222061

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:01:53

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

US3222061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:10:44

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3222061

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

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.

US3222061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

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

Collection date (dd MMM yyyy)	08 MAR 2021
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Collection time (00:00-23:59)	13:30 (24 HR)
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Collection date and time (derived)	08 MAR 2021 13:30
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US3222061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:36:56

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:36:56

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222061

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:01:53

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3222061

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:01:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222061

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

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

Visit date (dd MMM yyyy)	22 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3222061

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3222061

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Height	147.3 cm
Weight	58.9 kg
BMI (xxx.x)	27.14625

US3222061

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Height	147.3 cm
Weight	58.9 kg
BMI (xxx.x)	27.14625
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)	22 JAN 2021
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 14:35
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3222061

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Height	147.3 cm
Weight	58.9 kg
BMI (xxx.x)	27.14625
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)	22 JAN 2021
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 15:19
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

US3222061

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3222061

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 14:48 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 14:48

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

US3222061

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

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

Collection date (dd MMM yyyy)	22 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 JAN 2021 14:05
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US3222061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00 - 23:59)

14:07

Collection Date and Time (derived)

22 JAN 2021 14:07

US3222061

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 21:29:42

Generated On: 11 Aug 2021 22:01:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 21:29:42

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Were vital signs assessed? Yes ☐
No ☒

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 ☐
Axillary ☐
Other ☐

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 _____

Height (derived) _____

Weight (derived) _____

US3222061

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

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.

US3222061

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 MAR 2021

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

08 MAR 2021 13:30

US3222061

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 15:09:11

Generated On: 11 Aug 2021 22:01:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

AEID	
Adverse event	MASS ON RIGHT BREAST POSSITIVE FOR CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

305 of 1645

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 15:09:12

Generated On: 11 Aug 2021 22:01:53

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

Yes ☒

No ☐

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

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

308 of 1645

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2005
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

310 of 1645

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 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"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication METOPROLOL

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

312 of 1645

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication ELLIPTA (FLUTICASONE +
UMECLIDINIUM +
VILANTEROL)

Prophylaxis Yes ☒
No ☐

Indication COPD/EMPHASEMA

Dose per administration 100/65/25

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

314 of 1645

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 JAN 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication VENTOLIN

Prophylaxis Yes ☐
No ☒

Indication COPD/EMPHASEMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

316 of 1645

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JAN 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

320 of 1645

EAB) (1725)

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 13:36:55

Generated On: 11 Aug 2021 22:01:53

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

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 13:36:56

Generated On: 11 Aug 2021 22:01:53

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 13:36:56

Generated On: 11 Aug 2021 22:01:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 FEB 2021	MASTECTOMY RIGHT BREAST	Adverse Event	

US3222061

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 25 Mar 2021 17:12:47

Generated On: 11 Aug 2021 22:01:53

Date of dosing discontinuation (dd MMM yyyy)

14 SEP 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

AE #1 LEFT BREAST MASS, HER
ONCOLOGIST DIDNT WANT
HER TO RECEIVE THE SECOND
VACCINE AND THE PI KEPT
HER ON THE TRIAL.

US3222061

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:01:53

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

US3222061 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222061

Form: Participant Creation

Generated On: 11 Aug 2021 22:01:53

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'US3222061'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:27

US3222061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 14:33:33

US3222061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:28

US3222061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	10 Aug 2020 14:33:33

US3222061

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'SCRN'	System	10 Aug 2020 14:33:33

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:28

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '71'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'YEARS'	System	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '71'	System	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Female (F)'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:01:53

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:17

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered '10 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Aug 2020'	System	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2020'	System	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	10 Aug 2020 14:34:25

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Aug 2020 18:15:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:14:28

US3222061

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:01:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'I'	System	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:01:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	10 Aug 2020 17:12:58

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
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) (4), (b) (6)	12 Oct 2020 14:34:36
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:37:49
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)	10 Sep 2020 14:21:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 23:32:19
Data point term sent to Coder	System	10 Aug 2020 17:14:17
User entered 'COPD- Chronic Plmonary Disease'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '01 Jan 2006'	Crystal Paccione (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2006'	System	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2006'	System	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:14:14

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Response noted yet there is no concomitant medication listed for treatment of this condition. Please review and if applicable update or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 13:44:40
Query 'Per CDM: Response noted yet there is no concomitant medication listed for treatment of this condition. Please review and if applicable update or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:25:19
User opened query 'Per CDM: Response noted yet there is no concomitant medication listed for treatment of this condition. Please review and if applicable update or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:42:28
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)	12 Oct 2020 14:42:28
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:37:57
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)	10 Sep 2020 14:21:20
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:16:17

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EAB) (1725)

369 of 1645

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Aug 2020 17:16:17
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Aug 2020 17:15:17
User entered 'Emphysema'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:05
	(b) (4)	

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '01 Jan 2006'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2006'	System	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2006'	System	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:15:05

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:18:23
Data point term sent to Coder	System	10 Aug 2020 17:16:19
User entered 'Hyperlipidemia'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '01 Jan 2000'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2000'	System	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2000'	System	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:15:43

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Respiratory tract and pleural neoplasms malignant cell type unspecified NEC, PT: Lung neoplasm malignant, LLT: Lung cancer - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:18:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:18:23
Data point term sent to Coder	System	10 Aug 2020 17:17:21
User entered 'Lung Cancer'	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '01 Jan 2015'	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2015'	System	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2015'	System	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	10 Aug 2020 17:16:28

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 13:00:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 13:00:44
Data point term sent to Coder	System	01 Sep 2020 12:59:00
User entered 'Postmenopausal'	Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'I'	Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Amber Vasquez (b) (4)	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	01 Sep 2020 12:58:25

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 15:25:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 15:25:46
Data point term sent to Coder	System	13 Nov 2020 15:24:59
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '01 Jan 2010'	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Albert Garcia (b) (4)	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2010'	System	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2010'	System	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	13 Nov 2020 15:24:31

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 15:24:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 15:24:43
Data point term sent to Coder	System	22 Dec 2020 15:23:56
User entered 'ALLERGIES - SEASONAL'	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'UN UNK 2020'	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Albert Garcia (b) (4)	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'Jan 2020'	System	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '2020'	System	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered empty.	System	22 Dec 2020 15:23:20

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10:25'	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '10 Aug 2020 10:25'	System	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '147.3' cm	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 17:18:46
DataPoint set to visible.	(b) (4) System	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '58.9' kg	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46
DataPoint set to visible.	System	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
Amendment Manager: User entered '27.14625'	System	16 Sep 2020 23:49:38
User entered '27.1'	System	10 Aug 2020 17:18:46
DataPoint set to visible.	System	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'kg/m2'	System	10 Aug 2020 17:18:46
DataPoint set to visible.	System	10 Aug 2020 14:34:32

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 17:28:14
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:41
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:05:33
User entered '37.1' C	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4)	15 Sep 2020 20:51:41
User entered 'Oral (Oral)'	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:51:41
User entered '64'	Albert Garcia (b) (4)	10 Aug 2020 17:18:46
	(b) (4)	

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'bpm'	System	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:51:41
User entered '16'	Albert Garcia (b) (4)	15 Sep 2020 20:51:41
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46
	(b) (4)	

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'breaths/min'	System	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:51:41
User entered '150'	Albert Garcia (b) (4)	10 Aug 2020 17:18:46
	(b) (4)	

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'mmHg'	System	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 20:51:41
User entered '96'	Albert Garcia (b) (4)	15 Sep 2020 20:51:41
	(b) (4)	
	Crystal Paccione (b) (4)	10 Aug 2020 17:18:46
	(b) (4)	

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'mmHg'	System	10 Aug 2020 17:18:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46

US3222061

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46

US3222061

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Crystal Paccione (b) (4)	10 Aug 2020 17:18:58

US3222061

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	18 Sep 2020 18:52:23
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:52:23
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:52:23
User entered '10 Aug 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:52:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:52:19
User opened query 'Screening Physical is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	18 Sep 2020 18:52:19
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	18 Sep 2020 18:52:19
User entered '10 Jun 2020' reason for change: Data Entry Error	douglas winter (b) (4)	18 Sep 2020 18:52:19
Comment added 'SCREENING DATE AND PE DATE ARE THE SAME. PLEASE REMOVE THIS QUERY'.	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	Albert Garcia (b) (4)	15 Sep 2020 20:50:42
User entered '10 Aug 2020'	(b) (4)	
	Crystal Paccione (b) (4)	14 Sep 2020 19:30:24
	(b) (4)	10 Aug 2020 17:18:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:56:52
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'MH Updated' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 12:58:38
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 07:21:15
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:01:53

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'I'	Crystal Paccione (b) (4)	10 Aug 2020 17:19:58

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 17:00:05
User entered 'No (N)' reason for change: Data Entry Error	System	20 Aug 2020 17:00:05
User opened query 'Data is required. Please complete.' (Site from System).	Amber Vasquez (b) (4)	20 Aug 2020 17:00:05
User entered empty.	(b) (4)	
	System	10 Aug 2020 15:33:49
	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49
	(b) (4)	

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Retired'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'I'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '0'	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:01:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 15:33:49

US3222061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:12

US3222061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:12

US3222061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Clinic (Clinic)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:12

US3222061

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'VISIT1'	System	10 Aug 2020 17:20:12

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:49:34

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:14:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:14:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 14:49:34
User entered '185405' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:49:34

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 14:49:34

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 17:20:29

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:29

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:29

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:29

US3222061

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:01:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:20:29

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:31
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:42
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:13
User entered '147.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:34
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:20
User entered '58.9' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:31
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:42
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:13
User entered '147.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:34
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:20
User entered '58.9' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Pre-Dose (PREDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10:25'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '10 Aug 2020 10:25'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '37.1' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '64'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'bpm'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '16'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'breaths/min'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '150'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '96'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:31
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:45
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:42
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:13
User entered '147.3' cm	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:24:34
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 20:51:10
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
User closed query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 08:55:51
Query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:50
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:45:35
User opened query "'Per CDM: Per CCGs pages 15-16, 'Height and Weight' should be marked as 'ND.' Please review and update else clarify'." (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 18:07:20
User entered '58.9' kg	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Post-Dose (POSTDOSE)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User closed 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).	(b) (4) (b) (4), (b) (6)	13 Aug 2020 07:56:58
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 protocol correct' (Site from System).	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:26
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 17:23:10
User entered '11:55'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '10 Aug 2020 11:55'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '36.0' C	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Oral (Oral)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '54'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'bpm'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '16'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'breaths/min'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '144'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '93'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	10 Aug 2020 17:23:10

US3222061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:25:04

US3222061

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:25:04

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '11:18'	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '10 Aug 2020 11:18'	System	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'ONCE'	System	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 15:34:43

US3222061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:59

US3222061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4)	10 Aug 2020 17:23:59

US3222061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10:53'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:23:59

US3222061

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '10 Aug 2020 10:53'	System	10 Aug 2020 17:23:59

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10 Aug 2020'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '10:54'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '10 Aug 2020 10:54'	System	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Crystal Paccione (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	10 Aug 2020 17:24:21

US3222061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	10 Aug 2020 17:24:27

US3222061

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '1'	System	10 Aug 2020 17:24:27

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:46:53', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cb8a3cea-1f6b-408b-868d-602074336725' User entered 'Yes (Y)'	System	10 Aug 2020 15:47:23
	System	10 Aug 2020 15:47:23

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:05', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cb8a3cea-1f6b-408b-868d-602074336725' User entered '98.4'	System	10 Aug 2020 15:47:23
	System	10 Aug 2020 15:47:23

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:09', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cb8a3cea-1f6b-408b-868d-602074336725' User entered 'No (N)'	System	10 Aug 2020 15:47:23
	System	10 Aug 2020 15:47:23

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cb8a3cea-1f6b-408b-868d-602074336725' User entered '10 Aug 2020 11:47'	System	10 Aug 2020 15:47:23
	System	10 Aug 2020 15:47:23

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 11:38'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 14:08'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:44:42', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'bf1ad022-6262-4cca-abd1-c826aee45809' User entered 'Yes (Y)'	System	10 Aug 2020 19:45:06
	System	10 Aug 2020 19:45:06

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:44:49', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'bf1ad022-6262-4cca-abd1-c826aee45809' User entered '96.0'	System	10 Aug 2020 19:45:06
	System	10 Aug 2020 19:45:06

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:44:52', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'bf1ad022-6262-4cca-abd1-c826aee45809'	System	10 Aug 2020 19:45:06
User entered 'No (N)'	System	10 Aug 2020 19:45:06

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:03', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'bf1ad022-6262-4cca-abd1-c826aee45809' User entered '10 Aug 2020 15:45'	System	10 Aug 2020 19:45:06
	System	10 Aug 2020 19:45:06

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 15:03'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 2'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:19:28', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29'	System	11 Aug 2020 18:20:08
User entered 'Yes (Y)'	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:19:36', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29' User entered '97.0'	System	11 Aug 2020 18:20:08
	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:19:45', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29'	System	11 Aug 2020 18:20:08
User entered 'Yes (Y)'	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
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). 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 'PATIENT WAS CONTACTED' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 08:57:30
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:19:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29'	Amber Vasquez (b) (4)	01 Sep 2020 21:47:49
User entered '1'	System	11 Aug 2020 18:20:08
	System	11 Aug 2020 18:20:08
	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:19:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29' User entered '0'	System	11 Aug 2020 18:20:08
	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:04', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'cc6229e6-b4cf-4b01-a98d-48e003ce8f29'	System	11 Aug 2020 18:20:08
User entered '11 Aug 2020 14:20'	System	11 Aug 2020 18:20:08

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 3'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:04:38', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7376ea9f-da29-49ff-ae27-002a87bd3711' User entered 'Yes (Y)'	System	12 Aug 2020 16:04:59
	System	12 Aug 2020 16:04:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:04:45', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7376ea9f-da29-49ff-ae27-002a87bd3711' User entered '97.4'	System	12 Aug 2020 16:04:59
	System	12 Aug 2020 16:04:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:04:50', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7376ea9f-da29-49ff-ae27-002a87bd3711'	System	12 Aug 2020 16:04:59
User entered 'No (N)'	System	12 Aug 2020 16:04:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:04:55', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7376ea9f-da29-49ff-ae27-002a87bd3711' User entered '12 Aug 2020 12:04'	System	12 Aug 2020 16:04:59
	System	12 Aug 2020 16:04:59

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 4'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'da519624-430a-4af3-9394-0ee22b7b1574' User entered 'Yes (Y)'	System	13 Aug 2020 17:14:39
	System	13 Aug 2020 17:14:39

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'da519624-430a-4af3-9394-0ee22b7b1574' User entered '97.4'	System	13 Aug 2020 17:14:39
	System	13 Aug 2020 17:14:39

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'da519624-430a-4af3-9394-0ee22b7b1574'	System	13 Aug 2020 17:14:39
User entered 'No (N)'	System	13 Aug 2020 17:14:39

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:38', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'da519624-430a-4af3-9394-0ee22b7b1574' User entered '13 Aug 2020 13:14'	System	13 Aug 2020 17:14:39
	System	13 Aug 2020 17:14:39

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 5'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:12', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '52a9f6d8-aefe-4bda-8042-05984f080974' User entered 'Yes (Y)'	System	14 Aug 2020 20:42:34
	System	14 Aug 2020 20:42:34

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:22', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '52a9f6d8-aefe-4bda-8042-05984f080974' User entered '97.8'	System	14 Aug 2020 20:42:34
	System	14 Aug 2020 20:42:34

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:25', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '52a9f6d8-aefe-4bda-8042-05984f080974' User entered 'No (N)'	System	14 Aug 2020 20:42:34
	System	14 Aug 2020 20:42:34

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:28', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '52a9f6d8-aefe-4bda-8042-05984f080974' User entered '14 Aug 2020 16:42'	System	14 Aug 2020 20:42:34
	System	14 Aug 2020 20:42:34

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 6'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:13', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '728d82ce-e4a4-460c-a2f2-46707defa155' User entered 'Yes (Y)'	System	16 Aug 2020 12:31:28
	System	16 Aug 2020 12:31:28

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:20', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '728d82ce-e4a4-460c-a2f2-46707defa155' User entered '96.2'	System	16 Aug 2020 12:31:28
	System	16 Aug 2020 12:31:28

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:23', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '728d82ce-e4a4-460c-a2f2-46707defa155'	System	16 Aug 2020 12:31:28
User entered 'No (N)'	System	16 Aug 2020 12:31:28

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '728d82ce-e4a4-460c-a2f2-46707defa155'	System	16 Aug 2020 12:31:28
User entered '16 Aug 2020 08:31'	System	16 Aug 2020 12:31:28

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 7'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:20', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'b641d9c8-36d2-409e-9889-c58f77c728f8' User entered 'Yes (Y)'	System	16 Aug 2020 16:26:33
	System	16 Aug 2020 16:26:33

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:25', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'b641d9c8-36d2-409e-9889-c58f77c728f8' User entered '97.5'	System	16 Aug 2020 16:26:33
	System	16 Aug 2020 16:26:33

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:28', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'b641d9c8-36d2-409e-9889-c58f77c728f8' User entered 'No (N)'	System	16 Aug 2020 16:26:33
	System	16 Aug 2020 16:26:33

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'b641d9c8-36d2-409e-9889-c58f77c728f8' User entered '16 Aug 2020 12:26'	System	16 Aug 2020 16:26:33
	System	16 Aug 2020 16:26:33

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:29', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'efdd6cb6-f73e-49b6-b3d5-60759deb7a7d' User entered 'None (1)'	System	10 Aug 2020 15:48:01
	System	10 Aug 2020 15:48:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:35', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'efdd6cb6-f73e-49b6-b3d5-60759deb7a7d' User entered 'No (N)'	System	10 Aug 2020 15:48:01
	System	10 Aug 2020 15:48:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:40', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'efdd6cb6-f73e-49b6-b3d5-60759deb7a7d' User entered 'No (N)'	System	10 Aug 2020 15:48:01
	System	10 Aug 2020 15:48:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:46', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'efdd6cb6-f73e-49b6-b3d5-60759deb7a7d' User entered 'None (1)'	System	10 Aug 2020 15:48:01
	System	10 Aug 2020 15:48:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:47:53', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'efdd6cb6-f73e-49b6-b3d5-60759deb7a7d' User entered '10 Aug 2020 11:47'	System	10 Aug 2020 15:48:01
	System	10 Aug 2020 15:48:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 11:38'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 14:08'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:12', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7ac920b0-b84f-4f5f-90ef-d9b5dc035a13'	System	10 Aug 2020 19:45:35
User entered 'None (1)'	System	10 Aug 2020 19:45:35

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7ac920b0-b84f-4f5f-90ef-d9b5dc035a13'	System	10 Aug 2020 19:45:35
User entered 'No (N)'	System	10 Aug 2020 19:45:35

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:25', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7ac920b0-b84f-4f5f-90ef-d9b5dc035a13'	System	10 Aug 2020 19:45:35
User entered 'No (N)'	System	10 Aug 2020 19:45:35

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:28', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7ac920b0-b84f-4f5f-90ef-d9b5dc035a13'	System	10 Aug 2020 19:45:35
User entered 'None (1)'	System	10 Aug 2020 19:45:35

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:34', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7ac920b0-b84f-4f5f-90ef-d9b5dc035a13' User entered '10 Aug 2020 15:45'	System	10 Aug 2020 19:45:35
	System	10 Aug 2020 19:45:35

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 15:03'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 2'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:20', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '804a447b-a1aa-451d-8c2f-bc8a20e8b510'	System	11 Aug 2020 18:20:51
User entered 'Does not interfere with activity (2)'	System	11 Aug 2020 18:20:51

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '804a447b-a1aa-451d-8c2f-bc8a20e8b510' User entered 'No (N)'	System	11 Aug 2020 18:20:51
	System	11 Aug 2020 18:20:51

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:34', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '804a447b-a1aa-451d-8c2f-bc8a20e8b510' User entered 'No (N)'	System	11 Aug 2020 18:20:51
	System	11 Aug 2020 18:20:51

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:40', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '804a447b-a1aa-451d-8c2f-bc8a20e8b510' User entered 'None (1)'	System	11 Aug 2020 18:20:51
	System	11 Aug 2020 18:20:51

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:47', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '804a447b-a1aa-451d-8c2f-bc8a20e8b510'	System	11 Aug 2020 18:20:51
User entered '11 Aug 2020 14:20'	System	11 Aug 2020 18:20:51

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 3'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:16', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8f77de8d-df8b-43d1-bdb2-ad467665bc6f' User entered 'None (1)'	System	12 Aug 2020 16:05:38
	System	12 Aug 2020 16:05:38

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8f77de8d-df8b-43d1-bdb2-ad467665bc6f' User entered 'No (N)'	System	12 Aug 2020 16:05:38
	System	12 Aug 2020 16:05:38

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:24', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8f77de8d-df8b-43d1-bdb2-ad467665bc6f' User entered 'No (N)'	System	12 Aug 2020 16:05:38
	System	12 Aug 2020 16:05:38

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:29', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8f77de8d-df8b-43d1-bdb2-ad467665bc6f' User entered 'None (1)'	System	12 Aug 2020 16:05:38
	System	12 Aug 2020 16:05:38

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:36', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8f77de8d-df8b-43d1-bdb2-ad467665bc6f' User entered '12 Aug 2020 12:05'	System	12 Aug 2020 16:05:38
	System	12 Aug 2020 16:05:38

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 4'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:42', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ebe5c670-9305-4cd7-8310-f006ad2aefbd' User entered 'None (1)'	System	13 Aug 2020 17:15:04
	System	13 Aug 2020 17:15:04

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:46', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ebe5c670-9305-4cd7-8310-f006ad2aefbd' User entered 'No (N)'	System	13 Aug 2020 17:15:04
	System	13 Aug 2020 17:15:04

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:48', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ebe5c670-9305-4cd7-8310-f006ad2aefbd' User entered 'No (N)'	System	13 Aug 2020 17:15:04
	System	13 Aug 2020 17:15:04

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:14:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ebe5c670-9305-4cd7-8310-f006ad2aefbd' User entered 'None (1)'	System	13 Aug 2020 17:15:04
	System	13 Aug 2020 17:15:04

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:01', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ebe5c670-9305-4cd7-8310-f006ad2aefbd' User entered '13 Aug 2020 13:15'	System	13 Aug 2020 17:15:04
	System	13 Aug 2020 17:15:04

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 5'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ff8763c9-bdf1-4bf5-801d-5362ba6925d1'	System	14 Aug 2020 20:43:01
User entered 'None (1)'	System	14 Aug 2020 20:43:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:35', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ff8763c9-bdf1-4bf5-801d-5362ba6925d1'	System	14 Aug 2020 20:43:01
User entered 'No (N)'	System	14 Aug 2020 20:43:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:39', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ff8763c9-bdf1-4bf5-801d-5362ba6925d1'	System	14 Aug 2020 20:43:01
User entered 'No (N)'	System	14 Aug 2020 20:43:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:46', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ff8763c9-bdf1-4bf5-801d-5362ba6925d1'	System	14 Aug 2020 20:43:01
User entered 'None (1)'	System	14 Aug 2020 20:43:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:42:57', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ff8763c9-bdf1-4bf5-801d-5362ba6925d1' User entered '14 Aug 2020 16:42'	System	14 Aug 2020 20:43:01
	System	14 Aug 2020 20:43:01

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 6'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:31', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f5a43105-4373-49ea-9f78-95f563f4fe01'	System	16 Aug 2020 12:31:52
User entered 'None (1)'	System	16 Aug 2020 12:31:52

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:36', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f5a43105-4373-49ea-9f78-95f563f4fe01'	System	16 Aug 2020 12:31:52
User entered 'No (N)'	System	16 Aug 2020 12:31:52

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:41', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f5a43105-4373-49ea-9f78-95f563f4fe01' User entered 'No (N)'	System	16 Aug 2020 12:31:52
	System	16 Aug 2020 12:31:52

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:45', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f5a43105-4373-49ea-9f78-95f563f4fe01' User entered 'None (1)'	System	16 Aug 2020 12:31:52
	System	16 Aug 2020 12:31:52

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:31:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f5a43105-4373-49ea-9f78-95f563f4fe01' User entered '16 Aug 2020 08:31'	System	16 Aug 2020 12:31:52
	System	16 Aug 2020 12:31:52

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 7'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:37', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '07a8ef18-10cc-4ef9-96ec-57c7f4dc0e35'	System	16 Aug 2020 16:26:58
User entered 'None (1)'	System	16 Aug 2020 16:26:58

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:40', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '07a8ef18-10cc-4ef9-96ec-57c7f4dc0e35'	System	16 Aug 2020 16:26:58
User entered 'No (N)'	System	16 Aug 2020 16:26:58

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:44', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '07a8ef18-10cc-4ef9-96ec-57c7f4dc0e35'	System	16 Aug 2020 16:26:58
User entered 'No (N)'	System	16 Aug 2020 16:26:58

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:49', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '07a8ef18-10cc-4ef9-96ec-57c7f4dc0e35'	System	16 Aug 2020 16:26:58
User entered 'None (1)'	System	16 Aug 2020 16:26:58

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:26:55', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '07a8ef18-10cc-4ef9-96ec-57c7f4dc0e35' User entered '16 Aug 2020 12:26'	System	16 Aug 2020 16:26:58
	System	16 Aug 2020 16:26:58

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:04', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:07', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:13', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:24', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:26', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'None (0)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered 'No (N)'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T11:48:35', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '13da631b-909a-4910-97a0-268faf70c2e8' User entered '10 Aug 2020 11:48'	System	10 Aug 2020 15:48:40
	System	10 Aug 2020 15:48:40

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 11:38'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 14:08'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:40', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:45', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:48', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:53', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:45:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered 'None (0)'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:46:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3'	System	10 Aug 2020 19:46:10
User entered 'No (N)'	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-10T15:46:08', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f11e8188-6e1d-4031-8355-9dd34167abc3' User entered '10 Aug 2020 15:46'	System	10 Aug 2020 19:46:10
	System	10 Aug 2020 19:46:10

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '10 Aug 2020 15:03'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 2'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:20:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8'	System	11 Aug 2020 18:21:52
User entered 'No interference with activity (1)'	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8'	System	11 Aug 2020 18:21:52
User entered 'No interference with activity (1)'	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:14', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered 'None (0)'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:24', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered 'None (0)'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:29', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered 'None (0)'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered 'None (0)'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:38', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered 'No (N)'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-11T14:21:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '340cbab0-25ca-4314-8789-aa5dd82dc3f8' User entered '11 Aug 2020 14:21'	System	11 Aug 2020 18:21:52
	System	11 Aug 2020 18:21:52

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 3'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:42', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49' User entered 'None (0)'	System	12 Aug 2020 16:06:03
	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:45', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49' User entered 'None (0)'	System	12 Aug 2020 16:06:03
	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:48', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49' User entered 'None (0)'	System	12 Aug 2020 16:06:03
	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49' User entered 'None (0)'	System	12 Aug 2020 16:06:03
	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:53', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49' User entered 'None (0)'	System	12 Aug 2020 16:06:03
	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:55', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49'	System	12 Aug 2020 16:06:03
User entered 'None (0)'	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:05:58', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49'	System	12 Aug 2020 16:06:03
User entered 'No (N)'	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-12T12:06:01', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7f513461-23da-498b-bc5d-2438f51f8c49'	System	12 Aug 2020 16:06:03
User entered '12 Aug 2020 12:06'	System	12 Aug 2020 16:06:03

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 4'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:06', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:10', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:13', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:15', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:17', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'None (0)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:22', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2' User entered 'No (N)'	System	13 Aug 2020 17:15:29
	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-13T13:15:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd3ba0532-2c11-42a0-a838-9ad0e68f5eb2'	System	13 Aug 2020 17:15:29
User entered '13 Aug 2020 13:15'	System	13 Aug 2020 17:15:29

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 5'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:02', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:05', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:07', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:09', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:12', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:14', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'None (0)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:17', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered 'No (N)'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-14T16:43:22', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '768385a1-6b0d-488b-b49e-ea37e8e434a9' User entered '14 Aug 2020 16:43'	System	14 Aug 2020 20:43:26
	System	14 Aug 2020 20:43:26

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 6'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:03', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:05', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:08', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:10', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:12', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'None (0)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:15', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered 'No (N)'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T08:32:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c420b92b-0637-4607-8671-29397ac3f6cd' User entered '16 Aug 2020 08:32'	System	16 Aug 2020 12:32:23
	System	16 Aug 2020 12:32:23

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 7'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:03', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:07', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:09', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:12', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:14', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered 'None (0)'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c'	System	16 Aug 2020 16:27:31
User entered 'No (N)'	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-08-16T12:27:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'd9101384-003e-42dd-857f-339b0dd8356c' User entered '16 Aug 2020 12:27'	System	16 Aug 2020 16:27:31
	System	16 Aug 2020 16:27:31

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 15:34:43

US3222061

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:01:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 19:27:16

US3222061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '18 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:27:16

US3222061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:27:16

US3222061

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:27:16

US3222061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 19:27:47

US3222061

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Sep 2020 19:27:47

US3222061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:28:21

US3222061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '25 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:28:21

US3222061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:28:21

US3222061

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:28:21

US3222061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:29:04

US3222061

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Sep 2020 19:29:04

US3222061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 19:29:26

US3222061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '1 Sep 2020'	Amber Vasquez (b) (4)	14 Sep 2020 19:29:26

US3222061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:29:26

US3222061

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:29:26

US3222061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:29:31

US3222061

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Sep 2020 19:29:31

US3222061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:30:24

US3222061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:30:24

US3222061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Clinic (Clinic)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:30:24

US3222061

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'VISIT2'	System	14 Sep 2020 19:30:24

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4)	14 Sep 2020 19:31:05
	(b) (4)	

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '13:35'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '14 Sep 2020 13:35'	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '36.8' C	Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '70'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'bpm'	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '16'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'breaths/min'	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '126'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '78'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'mmHg'	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:31:05

US3222061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:31

US3222061

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:31:31

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'PATIENT HAS BEEN DIAGNOSED WITH BREST CANCER AND HAS UPCOMING TREATMENT. DOSING WITHHELD, BUT PATIENT WILL CONTINUE WITH FOLLOW-UPS.'	Amber Vasquez (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:32:48

US3222061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:10

US3222061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:10

US3222061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14:38'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:33:10

US3222061

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '14 Sep 2020 14:38'	System	14 Sep 2020 19:33:10

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '14:42'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '14 Sep 2020 14:42'	System	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:01:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Sep 2020 19:33:22

US3222061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	14 Sep 2020 19:33:28

US3222061

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Sep 2020 19:33:28

US3222061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:04

US3222061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '21 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 12:30:04

US3222061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:04

US3222061

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:30:04

US3222061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:16

US3222061

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Oct 2020 12:30:16

US3222061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:30

US3222061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '28 Sep 2020'	Albert Garcia (b) (4)	14 Oct 2020 12:30:30

US3222061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:30

US3222061

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:30:30

US3222061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:42

US3222061

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Oct 2020 12:30:42

US3222061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:54

US3222061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '5 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 12:30:54

US3222061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:54

US3222061

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:30:54

US3222061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:30:59

US3222061

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	14 Oct 2020 12:30:59

US3222061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:31:27

US3222061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '12 Oct 2020'	Albert Garcia (b) (4)	14 Oct 2020 12:31:27

US3222061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	14 Oct 2020 12:31:27

US3222061

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'VISIT3'	System	14 Oct 2020 12:31:27

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered empty.	System	14 Oct 2020 12:33:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10

US3222061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'No (N)'	Albert Garcia (b) (4)	14 Oct 2020 12:33:14

US3222061

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	Albert Garcia (b) (4)	14 Oct 2020 12:33:14

US3222061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	14 Oct 2020 12:33:28

US3222061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '12 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 12:33:28

US3222061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '12:30'	(b) (4) Albert Garcia (b) (4) (b) (4)	14 Oct 2020 12:33:28

US3222061

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '12 Oct 2020 12:30'	System	14 Oct 2020 12:33:28

US3222061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	Albert Garcia (b) (4)	14 Oct 2020 12:33:33

US3222061

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered '1'	System	14 Oct 2020 12:33:33

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 64'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:38:21
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:59:56
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 71'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-17T04:44:57', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'a1a3900e-4868-4bfa-89ac-adde2b612452'	System	17 Oct 2020 08:45:25
User entered 'No (N)'	System	17 Oct 2020 08:45:25

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-17T04:45:06', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'a1a3900e-4868-4bfa-89ac-adde2b612452'	System	17 Oct 2020 08:45:25
User entered 'No (N)'	System	17 Oct 2020 08:45:25

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-17T04:45:21', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'a1a3900e-4868-4bfa-89ac-adde2b612452' User entered '17 Oct 2020 04:45:21'	System	17 Oct 2020 08:45:25
	System	17 Oct 2020 08:45:25

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 78'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-24T08:52:20', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8fbdd693-c190-4936-ae3e-072fd96343ec' User entered 'No (N)'	System	24 Oct 2020 12:52:44
	System	24 Oct 2020 12:52:44

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-24T08:52:25', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8fbdd693-c190-4936-ae3e-072fd96343ec'	System	24 Oct 2020 12:52:44
User entered 'No (N)'	System	24 Oct 2020 12:52:44

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-10-24T08:52:42', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '8fbdd693-c190-4936-ae3e-072fd96343ec' User entered '24 Oct 2020 08:52:42'	System	24 Oct 2020 12:52:44
	System	24 Oct 2020 12:52:44

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 92'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-07T08:19:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '6620f43e-07c8-42d6-b117-d443abe59176' User entered 'No (N)'	System	07 Nov 2020 13:19:40
	System	07 Nov 2020 13:19:40

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-07T08:19:32', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '6620f43e-07c8-42d6-b117-d443abe59176' User entered 'No (N)'	System	07 Nov 2020 13:19:40
	System	07 Nov 2020 13:19:40

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-07T08:19:38', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '6620f43e-07c8-42d6-b117-d443abe59176' User entered '07 Nov 2020 08:19:38'	System	07 Nov 2020 13:19:40
	System	07 Nov 2020 13:19:40

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered 'Day 99'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-14T08:12:05', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ccd30789-9c5a-461e-8e89-b2ea6a25182d' User entered 'No (N)'	System	14 Nov 2020 13:12:20
	System	14 Nov 2020 13:12:20

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-14T08:12:11', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ccd30789-9c5a-461e-8e89-b2ea6a25182d' User entered 'No (N)'	System	14 Nov 2020 13:12:20
	System	14 Nov 2020 13:12:20

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-14T08:12:17', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'ccd30789-9c5a-461e-8e89-b2ea6a25182d' User entered '14 Nov 2020 08:12:17'	System	14 Nov 2020 13:12:20
	System	14 Nov 2020 13:12:20

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 15:34:43

US3222061

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:02:15
Data entry locked.	System	10 Aug 2020 15:34:43
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 15:34:43

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-21T09:11:48', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '2381c9f2-a3cc-4b87-b456-2ca5610da5b2'	System	21 Nov 2020 14:12:02
User entered 'No (N)'	System	21 Nov 2020 14:12:02

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-21T09:11:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '2381c9f2-a3cc-4b87-b456-2ca5610da5b2' User entered 'No (N)'	System	21 Nov 2020 14:12:02

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-21T09:11:58', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '2381c9f2-a3cc-4b87-b456-2ca5610da5b2' User entered '21 Nov 2020 09:11:58'	System	21 Nov 2020 14:12:02
	System	21 Nov 2020 14:12:02

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-25T09:07:08', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '5beb4225-8701-44aa-b2b3-ce862925253d'	System	25 Nov 2020 14:07:23
User entered 'No (N)'	System	25 Nov 2020 14:07:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-25T09:07:14', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '5beb4225-8701-44aa-b2b3-ce862925253d' User entered 'No (N)'	System	25 Nov 2020 14:07:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-11-25T09:07:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '5beb4225-8701-44aa-b2b3-ce862925253d' User entered '25 Nov 2020 09:07:19'	System	25 Nov 2020 14:07:23
	System	25 Nov 2020 14:07:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-02T08:29:18', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3cde84dc-fff0-4026-b146-948952a61b93'	System	02 Dec 2020 13:29:37
User entered 'No (N)'	System	02 Dec 2020 13:29:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-02T08:29:28', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3cde84dc-fff0-4026-b146-948952a61b93'	System	02 Dec 2020 13:29:37
User entered 'No (N)'	System	02 Dec 2020 13:29:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-02T08:29:34', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3cde84dc-fff0-4026-b146-948952a61b93'	System	02 Dec 2020 13:29:37
User entered '02 Dec 2020 08:29:34'	System	02 Dec 2020 13:29:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-09T08:10:40', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bc12f3f-308e-4d22-9f30-07e98f4b22c6' User entered 'No (N)'	System	09 Dec 2020 13:10:52
	System	09 Dec 2020 13:10:52

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-09T08:10:46', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bc12f3f-308e-4d22-9f30-07e98f4b22c6'	System	09 Dec 2020 13:10:52
User entered 'No (N)'	System	09 Dec 2020 13:10:52

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-09T08:10:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bc12f3f-308e-4d22-9f30-07e98f4b22c6' User entered '09 Dec 2020 08:10:51'	System	09 Dec 2020 13:10:52
	System	09 Dec 2020 13:10:52

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-18T13:02:09', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '553362f6-adbf-474e-84b4-e5f79a110e41'	System	18 Dec 2020 18:02:20
User entered 'No (N)'	System	18 Dec 2020 18:02:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-18T13:02:13', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '553362f6-adbf-474e-84b4-e5f79a110e41' User entered 'No (N)'	System	18 Dec 2020 18:02:20
	System	18 Dec 2020 18:02:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-18T13:02:18', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '553362f6-adbf-474e-84b4-e5f79a110e41' User entered '18 Dec 2020 13:02:18'	System	18 Dec 2020 18:02:20
	System	18 Dec 2020 18:02:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-23T09:10:01', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3b29c44c-e88d-422a-919d-cf4206a46399'	System	23 Dec 2020 14:10:20
User entered 'No (N)'	System	23 Dec 2020 14:10:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-23T09:10:08', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3b29c44c-e88d-422a-919d-cf4206a46399' User entered 'No (N)'	System	23 Dec 2020 14:10:20
	System	23 Dec 2020 14:10:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-23T09:10:14', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '3b29c44c-e88d-422a-919d-cf4206a46399' User entered '23 Dec 2020 09:10:14'	System	23 Dec 2020 14:10:20
	System	23 Dec 2020 14:10:20

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-30T09:46:39', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9470cfa4-9f21-4318-b33d-c381633dfb4e' User entered 'No (N)'	System	30 Dec 2020 14:46:51
	System	30 Dec 2020 14:46:51

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-30T09:46:43', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9470cfa4-9f21-4318-b33d-c381633dfb4e' User entered 'No (N)'	System	30 Dec 2020 14:46:51
	System	30 Dec 2020 14:46:51

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2020-12-30T09:46:48', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9470cfa4-9f21-4318-b33d-c381633dfb4e' User entered '30 Dec 2020 09:46:48'	System	30 Dec 2020 14:46:51
	System	30 Dec 2020 14:46:51

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-08T22:13:54', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bb6e325-e07f-492a-b200-f88016aa4c66'	System	09 Jan 2021 03:14:16
User entered 'No (N)'	System	09 Jan 2021 03:14:16

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-08T22:13:58', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bb6e325-e07f-492a-b200-f88016aa4c66'	System	09 Jan 2021 03:14:16
User entered 'No (N)'	System	09 Jan 2021 03:14:16

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-08T22:14:03', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '7bb6e325-e07f-492a-b200-f88016aa4c66'	System	09 Jan 2021 03:14:16
User entered '08 Jan 2021 22:14:03'	System	09 Jan 2021 03:14:16

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-13T09:51:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c1d7ffcc-610f-48a2-b50b-547ef8cdaf5e' User entered 'No (N)'	System	13 Jan 2021 14:51:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-13T09:51:31', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c1d7ffcc-610f-48a2-b50b-547ef8cdaf5e' User entered 'No (N)'	System	13 Jan 2021 14:51:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-13T09:51:33', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c1d7ffcc-610f-48a2-b50b-547ef8cdaf5e' User entered '13 Jan 2021 09:51:33'	System	13 Jan 2021 14:51:37
	System	13 Jan 2021 14:51:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-20T19:06:47', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e0ef8f6b-e8e7-48b1-ac90-aca9db4d9d54'	System	21 Jan 2021 00:06:57
User entered 'No (N)'	System	21 Jan 2021 00:06:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-20T19:06:51', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e0ef8f6b-e8e7-48b1-ac90-aca9db4d9d54'	System	21 Jan 2021 00:06:57
User entered 'No (N)'	System	21 Jan 2021 00:06:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-20T19:06:54', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e0ef8f6b-e8e7-48b1-ac90-aca9db4d9d54'	System	21 Jan 2021 00:06:57
User entered '20 Jan 2021 19:06:54'	System	21 Jan 2021 00:06:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-27T10:07:19', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '113e1d3f-d601-473d-b194-88f0f45d3e11'	System	27 Jan 2021 15:07:29
User entered 'No (N)'	System	27 Jan 2021 15:07:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-27T10:07:22', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '113e1d3f-d601-473d-b194-88f0f45d3e11' User entered 'No (N)'	System	27 Jan 2021 15:07:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-01-27T10:07:27', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '113e1d3f-d601-473d-b194-88f0f45d3e11' User entered '27 Jan 2021 10:07:27'	System	27 Jan 2021 15:07:29
	System	27 Jan 2021 15:07:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-03T08:41:34', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e32f19b8-1522-456f-82dc-4d9c549cb528' User entered 'No (N)'	System	03 Feb 2021 13:41:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-03T08:41:37', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e32f19b8-1522-456f-82dc-4d9c549cb528' User entered 'No (N)'	System	03 Feb 2021 13:41:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-03T08:41:41', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e32f19b8-1522-456f-82dc-4d9c549cb528' User entered '03 Feb 2021 08:41:41'	System	03 Feb 2021 13:41:45
	System	03 Feb 2021 13:41:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-10T08:11:56', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '41f666c5-5847-4b3d-8b34-4afdef0b16dc' User entered 'No (N)'	System	10 Feb 2021 13:12:07
	System	10 Feb 2021 13:12:07

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-10T08:11:59', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '41f666c5-5847-4b3d-8b34-4afdef0b16dc' User entered 'No (N)'	System	10 Feb 2021 13:12:07

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-10T08:12:02', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '41f666c5-5847-4b3d-8b34-4afdef0b16dc' User entered '10 Feb 2021 08:12:02'	System	10 Feb 2021 13:12:07
	System	10 Feb 2021 13:12:07

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-17T07:50:18', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f00dd111-a2d6-4097-ba25-33b88659e006' User entered 'No (N)'	System	17 Feb 2021 12:50:29
	System	17 Feb 2021 12:50:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-17T07:50:22', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f00dd111-a2d6-4097-ba25-33b88659e006'	System	17 Feb 2021 12:50:29
User entered 'No (N)'	System	17 Feb 2021 12:50:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-17T07:50:26', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'f00dd111-a2d6-4097-ba25-33b88659e006'	System	17 Feb 2021 12:50:29
User entered '17 Feb 2021 07:50:26'	System	17 Feb 2021 12:50:29

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-24T20:16:16-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '4c240ff3-9f0c-43ed-aa1e-58c6a102bf22'	System	25 Feb 2021 01:16:31
User entered 'No (N)'	System	25 Feb 2021 01:16:31

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-24T20:16:19-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '4c240ff3-9f0c-43ed-aa1e-58c6a102bf22'	System	25 Feb 2021 01:16:31
User entered 'No (N)'	System	25 Feb 2021 01:16:31

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-02-24T20:16:23-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '4c240ff3-9f0c-43ed-aa1e-58c6a102bf22'	System	25 Feb 2021 01:16:31
User entered '25 Feb 2021 01:16:23'	System	25 Feb 2021 01:16:31

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-05T14:19:12-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '49e805c5-ac98-469d-8ce3-e29e6c5f4e22'	System	05 Mar 2021 19:19:23
User entered 'No (N)'	System	05 Mar 2021 19:19:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-05T14:19:15-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '49e805c5-ac98-469d-8ce3-e29e6c5f4e22'	System	05 Mar 2021 19:19:23
User entered 'No (N)'	System	05 Mar 2021 19:19:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-05T14:19:20-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '49e805c5-ac98-469d-8ce3-e29e6c5f4e22'	System	05 Mar 2021 19:19:23
User entered '05 Mar 2021 14:19:20'	System	05 Mar 2021 19:19:23

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-10T08:29:49-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '126f553a-e31f-4990-85f8-92e39cadcd74'	System	10 Mar 2021 13:29:59
User entered 'No (N)'	System	10 Mar 2021 13:29:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-10T08:29:52-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '126f553a-e31f-4990-85f8-92e39cadcd74'	System	10 Mar 2021 13:29:59
User entered 'No (N)'	System	10 Mar 2021 13:29:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-10T08:29:55-05:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '126f553a-e31f-4990-85f8-92e39cadcd74'	System	10 Mar 2021 13:29:59
User entered '10 Mar 2021 08:29:55'	System	10 Mar 2021 13:29:59

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-17T07:29:01-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e39d9868-e4cb-40cc-a918-0fbfaa2c946c' User entered 'No (N)'	System	17 Mar 2021 11:29:14
	System	17 Mar 2021 11:29:14

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-17T07:29:05-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e39d9868-e4cb-40cc-a918-0fbfaa2c946c' User entered 'No (N)'	System	17 Mar 2021 11:29:14

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-17T07:29:11-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'e39d9868-e4cb-40cc-a918-0fbfaa2c946c' User entered '17 Mar 2021 07:29:11'	System	17 Mar 2021 11:29:14
	System	17 Mar 2021 11:29:14

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-24T07:25:43-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '687b4bc3-fec2-43b0-b1ef-3891a748c308'	System	24 Mar 2021 11:25:57
User entered 'No (N)'	System	24 Mar 2021 11:25:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-24T07:25:47-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '687b4bc3-fec2-43b0-b1ef-3891a748c308'	System	24 Mar 2021 11:25:57
User entered 'No (N)'	System	24 Mar 2021 11:25:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-03-24T07:25:55-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '687b4bc3-fec2-43b0-b1ef-3891a748c308' User entered '24 Mar 2021 07:25:55'	System	24 Mar 2021 11:25:57
	System	24 Mar 2021 11:25:57

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-02T09:34:40-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9978326d-1cdc-48ae-aafe-b850a98a4cc3'	System	02 Apr 2021 13:34:49
User entered 'No (N)'	System	02 Apr 2021 13:34:49

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-02T09:34:43-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9978326d-1cdc-48ae-aafe-b850a98a4cc3' User entered 'No (N)'	System	02 Apr 2021 13:34:49

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-02T09:34:47-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '9978326d-1cdc-48ae-aafe-b850a98a4cc3'	System	02 Apr 2021 13:34:49
User entered '02 Apr 2021 09:34:47'	System	02 Apr 2021 13:34:49

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-09T12:42:33-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c3597c66-9815-47cb-9a1c-d13ab846bb95'	System	09 Apr 2021 16:42:45
User entered 'No (N)'	System	09 Apr 2021 16:42:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-09T12:42:37-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c3597c66-9815-47cb-9a1c-d13ab846bb95'	System	09 Apr 2021 16:42:45
User entered 'No (N)'	System	09 Apr 2021 16:42:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-09T12:42:40-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'c3597c66-9815-47cb-9a1c-d13ab846bb95'	System	09 Apr 2021 16:42:45
User entered '09 Apr 2021 12:42:40'	System	09 Apr 2021 16:42:45

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-16T14:17:05-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'be0f135b-62e9-4163-a46f-4e176d0da2fc'	System	16 Apr 2021 18:17:18
User entered 'No (N)'	System	16 Apr 2021 18:17:18

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-16T14:17:10-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'be0f135b-62e9-4163-a46f-4e176d0da2fc'	System	16 Apr 2021 18:17:18
User entered 'No (N)'	System	16 Apr 2021 18:17:18

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-16T14:17:13-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: 'be0f135b-62e9-4163-a46f-4e176d0da2fc' User entered '16 Apr 2021 14:17:13'	System	16 Apr 2021 18:17:18
	System	16 Apr 2021 18:17:18

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-23T12:00:24-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '281a3923-9b3a-4a87-b0c6-b0134eef54b8' User entered 'No (N)'	System	23 Apr 2021 16:01:01
	System	23 Apr 2021 16:01:01

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-23T12:00:27-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '281a3923-9b3a-4a87-b0c6-b0134eef54b8' User entered 'No (N)'	System	23 Apr 2021 16:01:01
	System	23 Apr 2021 16:01:01

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-23T12:00:32-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '281a3923-9b3a-4a87-b0c6-b0134eef54b8' User entered '23 Apr 2021 12:00:32'	System	23 Apr 2021 16:01:01
	System	23 Apr 2021 16:01:01

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-28T07:22:56-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '542bb8cb-aa37-4e18-9668-4c0776415f31'	System	29 Apr 2021 04:18:37
User entered 'No (N)'	System	29 Apr 2021 04:18:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Have you been exposed to someone with 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 (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-28T07:23:00-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '542bb8cb-aa37-4e18-9668-4c0776415f31' User entered 'No (N)'	System	29 Apr 2021 04:18:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6430400B-1196-40D1-85F6-7981DCD30BC4)', Time: '2021-04-28T07:23:03-04:00', User OID: 'PatientReportedOutcome (US3222061)', ODM File OID: '542bb8cb-aa37-4e18-9668-4c0776415f31'	System	29 Apr 2021 04:18:37
User entered '28 Apr 2021 07:23:03'	System	29 Apr 2021 04:18:37

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 16:59:56

US3222061

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:01:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:59:56
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 16:59:56

US3222061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:24:01

US3222061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:24:01

US3222061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:24:01

US3222061

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:24:01

US3222061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:10:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:24:16

US3222061

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:40:10
User entered 'I'	System	17 Nov 2020 21:24:16

US3222061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:46:48

US3222061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '10 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:46:48

US3222061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:46:48

US3222061

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:46:48

US3222061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:46:59

US3222061

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User entered 'I'	System	04 Jan 2021 18:46:59

US3222061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:47:28

US3222061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '04 Jan 2021'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:47:28

US3222061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:47:28

US3222061

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:47:28

US3222061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 18:47:37

US3222061

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User entered 'I'	System	04 Jan 2021 18:47:37

US3222061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	08 Mar 2021 19:21:43

US3222061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '02 Mar 2021'	Diana Toney (b) (4)	08 Mar 2021 19:21:43

US3222061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Diana Toney (b) (4) (b) (4)	08 Mar 2021 19:21:43

US3222061

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:21:43

US3222061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	08 Mar 2021 19:21:48

US3222061

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:30:31
User entered 'I'	System	08 Mar 2021 19:21:48

US3222061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	08 Mar 2021 19:22:06

US3222061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '08 Mar 2021'	Diana Toney (b) (4)	08 Mar 2021 19:22:06

US3222061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	08 Mar 2021 19:22:06

US3222061

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'VISIT4'	System	08 Mar 2021 19:22:06

US3222061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'No (N)'	Diana Toney (b) (4)	08 Mar 2021 19:22:19

US3222061

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:22:19

US3222061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	08 Mar 2021 19:22:42

US3222061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '08 Mar 2021'	Diana Toney (b) (4)	08 Mar 2021 19:22:42

US3222061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '13:30'	Diana Toney (b) (4)	08 Mar 2021 19:22:42

US3222061

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered '08 Mar 2021 13:30'	System	08 Mar 2021 19:22:42

US3222061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	08 Mar 2021 19:22:53

US3222061

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:03:46
User entered 'I'	System	08 Mar 2021 19:22:53

US3222061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:52:18

US3222061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:52:18

US3222061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:52:18

US3222061

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:52:18

US3222061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:52:25

US3222061

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 12:52:25

US3222061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:14

US3222061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:14

US3222061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:14

US3222061

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

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:51:14

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '0'	(b) (4) Diana Toney (b) (4)	08 Mar 2021 19:19:11
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 03:33:47

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	Diana Toney (b) (4)	08 Mar 2021 19:19:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:33:47

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Not Administered (NA)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered empty.	System	22 Jan 2021 20:51:39

US3222061

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

Form: Unblinding

Generated On: 11 Aug 2021 22:01:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'I'	System	22 Jan 2021 20:51:39

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '147.3' cm	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '58.9' kg	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '27.14625'	System	22 Jan 2021 20:54:04
DataPoint set to visible.	System	22 Jan 2021 20:51:39

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '147.3' cm	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '58.9' kg	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '27.14625'	System	22 Jan 2021 20:54:04
DataPoint set to visible.	System	22 Jan 2021 20:51:39

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '14:35'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '22 Jan 2021 14:35'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '36.6' C	Diana Toney (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '89'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'bpm'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '16'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'breaths/min'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '124'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'mmHg'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '90'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'mmHg'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '147.3' cm	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '58.9' kg	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:01:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '27.14625'	System	22 Jan 2021 20:54:04
DataPoint set to visible.	System	22 Jan 2021 20:51:39

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '15:19'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '22 Jan 2021 15:19'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '36.6' C	Diana Toney (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Oral (Oral)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '81'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'bpm'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '16'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'breaths/min'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '138'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'mmHg'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '94'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:04

US3222061

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'mmHg'	System	22 Jan 2021 20:54:04

US3222061

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:15

US3222061

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:15

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	Diana Toney (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'mRNA-1273'	System	22 Jan 2021 20:54:51
DataPoint set to visible.	System	22 Jan 2021 20:51:39

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '14:48'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '22 Jan 2021 14:48'	System	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Left Arm (LEFT ARM)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'ONCE'	System	22 Jan 2021 20:54:51

US3222061

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

Form: Exposure

Generated On: 11 Aug 2021 22:01:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 20:54:51

US3222061

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:17

US3222061

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:17

US3222061

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '14:05'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:17

US3222061

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '22 Jan 2021 14:05'	System	22 Jan 2021 20:55:17

US3222061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:31

US3222061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '22 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:31

US3222061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:53

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '14:07'	Diana Toney (b) (4)	22 Jan 2021 20:55:31

US3222061

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered '22 Jan 2021 14:07'	System	22 Jan 2021 20:55:31

US3222061

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

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	22 Jan 2021 20:55:37

US3222061

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

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:28
User entered 'I'	System	22 Jan 2021 20:55:37

US3222061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:29:42
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 11:12:34

US3222061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:29:42
User entered '01 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 11:12:34

US3222061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:29:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 11:12:34

US3222061

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:01:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:29:42
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 11:12:34

US3222061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:29:42
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	02 Mar 2021 11:12:40

US3222061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User entered 'I'	System	02 Mar 2021 11:12:40

US3222061

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:01:53

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:30:32
User entered 'I'	System	02 Mar 2021 11:12:40
DataPoint set to visible.	System	02 Mar 2021 11:12:40

US3222061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	08 Mar 2021 19:20:05

US3222061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:26:00
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'OOW BY 4 DAYS DEVIATION CREATED' (Site from System).	Diana Toney (b) (4) (b) (4)	08 Mar 2021 23:03:14
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Mar 2021 19:20:05
User entered '08 Mar 2021'	Diana Toney (b) (4) (b) (4)	08 Mar 2021 19:20:05

US3222061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	08 Mar 2021 19:20:05

US3222061

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:01:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered 'OLD29'	System	08 Mar 2021 19:20:05

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'No (N)'	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered empty.	System	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered empty.	System	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered empty.	System	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered empty.	System	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered empty.	System	08 Mar 2021 19:20:24

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13

US3222061

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:01:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13

US3222061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'No (N)'	Diana Toney (b) (4)	08 Mar 2021 19:20:33

US3222061

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:01:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered empty.	Diana Toney (b) (4)	08 Mar 2021 19:20:33

US3222061

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'Yes (Y)'	Diana Toney (b) (4)	08 Mar 2021 19:20:58

US3222061

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '08 Mar 2021'	Diana Toney (b) (4)	08 Mar 2021 19:20:58

US3222061

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered '13:30'	Diana Toney (b) (4)	08 Mar 2021 19:20:58

US3222061

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:04:13
User entered '08 Mar 2021 13:30'	System	08 Mar 2021 19:20:58

US3222061

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:01:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Amber Vasquez (b) (4)	14 Sep 2020 19:33:59
	(b) (4)	
User entered 'No (N)'	Crystal Paccione (b) (4)	10 Aug 2020 17:24:41
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per MM, please confirm if the breast mass is benign or malignant.' (Site from DM).	(b) (4)	
Query 'Per MM, please confirm if the breast mass is benign or malignant.' answered with 'SUBJECT WAS SCHEDULED TO HAVE A BIOPSY, BUT THOSE RESULTS HAVE NOT BEEN REPORTED TO THIS SITE. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:51:27
	Albert Garcia (b) (4)	18 Dec 2020 16:59:00
	(b) (4)	
User opened query 'Per MM, please confirm if the breast mass is benign or malignant.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 23:20:37
User coded data point as SOC: Reproductive system and breast disorders, HLG: Breast disorders, HLT: Breast disorders NEC, PT: Breast mass, LLT: Breast mass - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 06:26:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 06:26:46
Data point term sent to Coder	(b) (4)	
User entered 'MASS ON RIGHT BREAST POSSITIVE FOR CANCER'	System	14 Sep 2020 19:36:50
	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '4 Sep 2020'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	14 Sep 2020 19:36:44
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4)	14 Sep 2020 19:36:44
User entered '00:00' reason for change: Data Entry Error	Amber Vasquez (b) (4)	14 Sep 2020 19:36:32
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 19:36:06
User entered '00:01'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:36:44
User entered '4 Sep 2020 00:00'	System	14 Sep 2020 19:36:32
User entered '4 Sep 2020 00:01'	System	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Oct 2020 13:17:50
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Oct 2020 15:23:23
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:23:23
Query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' answered with 'AWAITING DISCHARGE SUMMARY.' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:22:58
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Oct 2020 15:22:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:22:48
User opened query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 17:40:41
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 13:17:17
Comment added 'PATIENT HAS A DX OF CANCER AND WILL BE WITHDRAWN FROM IP. HOWEVER, IP IS NOT RELATED TO THE RECENT DX.'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:37:46
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:36:06
User entered 'Not Related (NOT RELATED)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:21:59
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 12:48:01
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	18 Nov 2020 12:46:53
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:09:03
User entered 'Not Applicable (NOT APPLICABLE)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		06 Mar 2021 14:49:33
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	06 Mar 2021 14:49:33
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	06 Mar 2021 14:49:01
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:39:06
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:23:55
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:56:45
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
	(b) (4)	
Signature has been broken.	Crystal Paccione (b) (4)	05 Apr 2021 19:05:22
	(b) (4)	
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM). Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'WE ARE AWAITING THE PT TO PROVIDE AN UPDATE' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:39:03
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:24:22
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 04:56:51
	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 19:37:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	14 Sep 2020 19:37:56
User opened query 'Data is required. Please complete.' (Site from System).	Amber Vasquez (b) (4)	14 Sep 2020 19:37:56
User entered empty.	(b) (4)	
	System	14 Sep 2020 19:36:06
	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	14 Sep 2020 19:36:06
	(b) (4)	

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	12 Oct 2020 15:23:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 15:23:23
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 15:22:48
User entered empty.	Amber Vasquez (b) (4) (b) (4)	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 15:23:23
User entered '1'	System	12 Oct 2020 15:22:48
User entered '0'	System	14 Sep 2020 19:36:06

US3222061

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:01:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 19:36:06

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:01:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:31:53

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 11:33:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:33:50
Data point term sent to Coder	System	16 Sep 2020 11:33:18
User entered 'ATORVASTATIN'	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:32:56

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4)	13 Nov 2020 15:18:48
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '20'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'unknown (UNKNOWN)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '01 Jan 2005'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	16 Sep 2020 11:32:56
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:32:56

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:32:56

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:32:56

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 11:36:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:36:52
Data point term sent to Coder User entered 'LOSARTAN'	System Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:35:22 16 Sep 2020 11:34:23

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:19:35
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 15:24:56
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:16:25
User entered 'HYPERTENSION'	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:34:23

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '50'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '01 Jan 2010'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	16 Sep 2020 11:34:23
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 11:34:23

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 11:34:23

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 11:34:23

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Sep 2020 11:36:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 11:36:53
Data point term sent to Coder	System	16 Sep 2020 11:36:22
User entered 'METOPROLOL'	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:35:38

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'HYPERTENSION'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '25'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'mg (mg)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'once daily (QD)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '01 Jan 2018'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	16 Sep 2020 11:35:38
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 11:35:38

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 11:35:38

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Sep 2020 11:35:38

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:07:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 12:07:58
Data point term sent to Coder	System	12 Oct 2020 15:26:44
Coding entries removed.	Albert Garcia (b) (4)	12 Oct 2020 15:25:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: FLUTICASONE FUROATE;UMECLIDINIUM BROMIDE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: TRELEGY ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:02:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 12:02:42
Data point term sent to Coder	System	21 Sep 2020 18:13:54
User closed query 'CDM-Coding: The trade name ELIPTA cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	21 Sep 2020 18:13:05

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM-Coding: The trade name ELIPTA cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Updated. ' (Site from System).	Thais Truffa (b) (4)	21 Sep 2020 18:13:05
User entered 'ELLIPTA (Fluticasone + umeclidinium + vilanterol)' reason for change: Data Entry Error	Thais Truffa (b) (4)	21 Sep 2020 18:12:58
User opened query 'CDM-Coding: The trade name ELIPTA cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	17 Sep 2020 03:16:41
Data point term sent to Coder	System	16 Sep 2020 11:37:22
User entered 'ELIPTA'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per CDM: Please note that there is no Medical History that matches this Con Med indication 'COPD/EMPHASEMA'. Please review Con Med use and add a medical condition and all applicable details to the Medical History eCRF if appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:19:01
Query 'Per CDM: Please note that there is no Medical History that matches this Con Med indication 'COPD/EMPHASEMA'. Please review Con Med use and add a medical condition and all applicable details to the Medical History eCRF if appropriate.'	Albert Garcia (b) (4) (b) (4)	23 Oct 2020 13:47:07
answered with 'BOTH INDICATINS ARE LISTED IN THE MH, HOWEVER MEDICATION CAN BE AND IS TAKEN FOR BOTH. ' (Site from DM).		
User opened query 'Per CDM: Please note that there is no Medical History that matches this Con Med indication 'COPD/EMPHASEMA'. Please review Con Med use and add a medical condition and all applicable details to the Medical History eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:43:43
User entered 'COPD/EMPHASEMA' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	12 Oct 2020 15:25:45
User entered 'COPD'	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:36:41

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '100/65/25'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Other (OTHER)'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'MCG'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'unknown (UNKNOWN)'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 10:18:30
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4)	13 Nov 2020 15:20:32
User entered '01 Jan 2006' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:17:17
User entered '01 Jan 2005'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	16 Sep 2020 11:36:41
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:36:41

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:36:41

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:36:41

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 04:58:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 04:58:22
Data point term sent to Coder	System	12 Oct 2020 15:26:43
Coding entries removed.	Albert Garcia (b) (4)	12 Oct 2020 15:25:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 11:39:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 11:39:41
Data point term sent to Coder	System	16 Sep 2020 11:38:23
User entered 'VENTOLIN'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:20:12
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	16 Nov 2020 12:51:09
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	16 Nov 2020 12:51:03
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 23:18:44
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'COPD/EMPHASEMA' reason for change: Data Entry Error	Albert Garcia (b) (4)	12 Oct 2020 15:25:58
	(b) (4)	
User entered 'COPD'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '90'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:08:52
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:08:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Other (OTHER)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 11:59:06
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 17:10:14
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 17:08:52
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 17:08:52
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 03:31:40
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'MCG'	(b) (4) Amber Vasquez (b) (4) (b) (4)	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'as needed (PRN)'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '01 Jan 2006'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered '0'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered empty.	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	16 Sep 2020 11:37:30
	(b) (4)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 11:37:30

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:33:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:33:24
Data point term sent to Coder	System	04 Nov 2020 15:17:44
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'SEASONAL INFLUENZA'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'UNK' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 15:21:03
User entered '1'	Albert Garcia (b) (4)	04 Nov 2020 15:17:01
	(b) (4)	
	(b) (4), (b) (6)	

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	13 Nov 2020 15:21:03
User entered 'Other (OTHER)'	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration' .Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 10:20:37
Query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration' .Please review and update the data as appropriate,else clarify.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 15:21:10
User entered empty; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	13 Nov 2020 15:21:03
User opened query 'Per CDM: Response for Dose unit is recorded as "Injection", however it signifies 'Route of administration' .Please review and update the data as appropriate,else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 16:24:46
User entered 'INJECTION'	(b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User entered empty.	System	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User entered empty.	System	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:13:00
User entered empty.	System	04 Nov 2020 15:17:01

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:21:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:21:28
Data point term sent to Coder	System	04 Nov 2020 15:20:49
User entered 'FLONASE'	(b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Dec 2020 08:47:49
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	22 Dec 2020 15:24:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 10:23:09
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '50'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'UN UNK 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:01:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 15:20:02

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:01:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:33:02
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
Signature has been broken.	Crystal Paccione (b) (4)	05 Apr 2021 19:05:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Paccione (b) (4)	05 Apr 2021 19:05:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 15:42:44

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:01:53

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
	(b) (4)	
User entered '12 Feb 2021'	Crystal Paccione (b) (4)	05 Apr 2021 19:06:22
	(b) (4)	

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:01:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
	(b) (4)	
User entered 'MASTECTOMY RIGHT BREAST'	Crystal Paccione (b) (4)	05 Apr 2021 19:06:22
	(b) (4)	

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:01:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
	(b) (4)	
User entered 'Adverse Event (AE)'	Crystal Paccione (b) (4)	05 Apr 2021 19:06:22
	(b) (4)	

US3222061

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:01:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:36:56
	(b) (4)	
User entered empty.	Crystal Paccione (b) (4)	05 Apr 2021 19:06:22
	(b) (4)	

US3222061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:01:53

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:25:34
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered '14 Sep 2020'	(b) (4) douglas winter (b) (4)	09 Dec 2020 17:18:50

US3222061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:01:53

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:25:34
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Mar 2021 14:49:33
Signature has been broken.	Amber Vasquez (b) (4)	06 Mar 2021 14:49:01
User entered 'Other (OTHER)' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Mar 2021 14:49:01
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 15:09:13
User entered 'AE (specify) (ADVERSE EVENT)'	douglas winter (b) (4)	09 Dec 2020 17:18:50

US3222061

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:01:53

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:25:34
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:12:47
User closed query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 13:51:09
User entered 'AE #1 LEFT BREAST MASS, HER ONCOLOGIST DIDNT WANT HER TO RECEIVE THE SECOND VACCINE AND THE PI KEPT HER ON THE TRIAL.' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:50:04
Query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' answered with 'updated date to reflect AE #1 in specify field' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:49:54
Signature has been broken.	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:49:33
User entered 'AE #1 LEFT BREAST MASSS, HER ONCOLOGIST DIDNT WANT HER TO RECEIVE THE SECOND VACCINE AND THE PI KEPT HER ON THE TRIAL.' reason for change: Data Entry Error	Amber Vasquez (b) (4) (b) (4)	06 Mar 2021 14:49:33
User opened query 'Per CDM: Per sponsor review, please update specify field to include both AE, number sign, and number. (i.e. AE #1).' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:21:06
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 15:09:13
User entered 'LEFT BREAST MASSS, HER ONCOLOGIST DIDNT WANT HER TO RECEIVE THE SECOND VACCINE AND THE PI KEPT HER ON THE TRIAL.'	douglas winter (b) (4) (b) (4)	09 Dec 2020 17:18:50