

US3192730 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:04:44

All time stamps listed in this document are displayed in GMT

US3192730

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

[Participant ID](#)

US3192730

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

US3192730

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Condition	BREAST CANCER
Start date (dd MMM yyyy)	31 JUL 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2010
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2008
Start Year (derived)	2008
Stop Month and Year (derived)	APR 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Condition	FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Condition	TACHYCARDIA
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Condition	BOTOX
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	4 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:00 (24 HR)
Vital Signs Date and Time (derived)	4 OCT 2020 11:00
Height (<i>xxx.x</i>)	60 in
Weight (<i>xxx.x</i>)	128.8 lb
BMI (<i>xxx.x</i>)	25.20712 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Date of assessment (dd MMM yyyy) 4 OCT 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) UN UNK 2000

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:00

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:00

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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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

What was the date of randomization? (dd MMM yyyy) 04 OCT 2020

What was the participant's randomization number? 191447

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☐
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

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)	4 OCT 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	4 OCT 2020 11:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

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)	4 OCT 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	4 OCT 2020 12:06
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

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) 4 OCT 2020

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

Treatment Date and Time (derived) 4 OCT 2020 11:36

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 OCT 2020
Collection time (00:00-23:59)	11:15 (24 HR)
Collection date and time (derived)	4 OCT 2020 11:15

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Collection date (dd MMM yyyy)			4 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:10	4 OCT 2020 11:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:11

PC Open Date & Time

04 OCT 2020 11:56

PC Close Date & Time

04 OCT 2020 14:26

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 04 OCT 2020 15:21

PC Close Date & Time 05 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

97.5 °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

06 OCT 2020 14:41

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 14:16

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

08 OCT 2020 13:50

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

09 OCT 2020 12:07

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

10 OCT 2020 12:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

04 OCT 2020 12:12

PC Open Date & Time

04 OCT 2020 11:56

PC Close Date & Time

04 OCT 2020 14:26

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

04 OCT 2020 15:21

PC Close Date & Time

05 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

06 OCT 2020 14:42

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

07 OCT 2020 14:16

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

08 OCT 2020 13:51

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

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

09 OCT 2020 12:08

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

10 OCT 2020 12:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

No ☒

Yes ☐

PC Time stamp	04 OCT 2020 12:13
PC Open Date & Time	04 OCT 2020 11:56
PC Close Date & Time	04 OCT 2020 14:26

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 15:21

PC Close Date & Time

05 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

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 ☐

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

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 ☒

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 14:43
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

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 ☒

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 14:17
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 13:51
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

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 ☒

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:08
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

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 ☒

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EAB) (1725)

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 12:06
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3192730

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 04:11:37

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 04:11:37

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

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)	6 NOV 2020
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	6 NOV 2020 08:12
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 NOV 2020

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

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

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 DECLINED DOSE 2 DUE TO HX OF TACHYCARDIA.

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? _____

US3192730

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 NOV 2020
Collection time (00:00-23:59)	08:57 (24 HR)
Collection date and time (derived)	6 NOV 2020 08:57

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Collection date (dd MMM yyyy)			6 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:02	6 NOV 2020 09:02
Nasopharyngeal Swab 2	No		

US3192730

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments
If Contact Not Made, please provide Comments
-LVM ASKING PATIENT TO
GIVE US A CALL BACK (NOV 13,
20)
-LVM 2ND ATTEMPT (NOV 16,
20)
-LVM 3RD ATTEMPT (NOV 16,
20)

US3192730

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:00

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 DEC 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

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	11:12 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 11:12
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192730

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3192730

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 DEC 2020

Collection time (00:00-23:59)

11:50 (24 HR)

Collection date and time (derived)

7 DEC 2020 11:50

US3192730

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:28:11

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2020 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 12:55:26
Patient Cloud Open Date & Time	08 DEC 2020 00:01
Patient Cloud Close Date & Time	12 DEC 2020 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 06:16:50
Patient Cloud Open Date & Time	15 DEC 2020 00:01
Patient Cloud Close Date & Time	19 DEC 2020 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 DEC 2020 06:24:02
Patient Cloud Open Date & Time	22 DEC 2020 00:01
Patient Cloud Close Date & Time	26 DEC 2020 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 DEC 2020 05:55:27
Patient Cloud Open Date & Time	29 DEC 2020 00:01
Patient Cloud Close Date & Time	02 JAN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 08:19:07
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

12 JAN 2021 06:51:47

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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	19 JAN 2021 06:22:45
Patient Cloud Open Date & Time	19 JAN 2021 00:01
Patient Cloud Close Date & Time	23 JAN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 17:52:58

Patient Cloud Open Date & Time

26 JAN 2021 00:01

Patient Cloud Close Date & Time

30 JAN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 FEB 2021 11:13:49

Patient Cloud Open Date & Time

02 FEB 2021 00:01

Patient Cloud Close Date & Time

06 FEB 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 12:04:06
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <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 checked="" 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)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 FEB 2021 00:10:03
Patient Cloud Open Date & Time	16 FEB 2021 00:01
Patient Cloud Close Date & Time	20 FEB 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

23 FEB 2021 06:11:56

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

02 MAR 2021 06:58:50

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

11 MAR 2021 12:00:45

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 23:20:30

Patient Cloud Open Date & Time

16 MAR 2021 00:01

Patient Cloud Close Date & Time

20 MAR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

26 MAR 2021 18:14:44

Patient Cloud Open Date & Time

23 MAR 2021 00:01

Patient Cloud Close Date & Time

27 MAR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 12:20:55

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 18:06:26

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 13:31:55

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

20 APR 2021 09:49:32

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

27 APR 2021 04:14:42

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

31 JUL 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 <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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	14 AUG 2021 23:59
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US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐ Yes ☐

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
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Patient Cloud Close Date & Time	09 OCT 2021 23:59
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US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

19 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	30 OCT 2021 23:59
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US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	18 DEC 2021 23:59
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US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐
Yes ☐

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

01 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

26 FEB 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

01 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

26 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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="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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐ Yes ☐

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Open Date & Time](#)

28 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUL 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

19 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

10 SEP 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	29 OCT 2022 23:59
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US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

05 NOV 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

12 NOV 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Close Date & Time](#)

19 NOV 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

22 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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°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 ☐

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

[Patient Cloud Open Date & Time](#)

29 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2022 23:59

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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"/>

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2022 00:01
Patient Cloud Close Date & Time	10 DEC 2022 23:59

US3192730

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:04:44

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
Yes	No	02 MAR 2021 06:59:41

US3192730

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:36:14

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:36:14

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 19:45:22

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 19:45:22

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 11 Aug 2021 22:04:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 11 Aug 2021 22:04:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 APR 2021
Time of assessment (00:00-23:59)	08:12 (24 HR)
Vital Signs Date and Time (derived)	23 APR 2021 08:12
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192730

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 11 Aug 2021 22:04:44

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.

US3192730

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 APR 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

23 APR 2021 08:20

US3192730

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 17:54:10

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192730

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:04:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3192730

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

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

Visit date (dd MMM yyyy)	13 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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US3192730

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:26:36

Generated On: 11 Aug 2021 22:04:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 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>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input 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	1
Continuing with mRNA-1273	1

US3192730

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Height	60 in
Weight	127.4 lb
BMI (xxx.x)	24.93313

US3192730

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Height	60 in
Weight	127.4 lb
BMI (xxx.x)	24.93313
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)	13 JAN 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 12:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3192730

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Height	60 in
Weight	127.4 lb
BMI (xxx.x)	24.93313
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)	13 JAN 2021
Time of assessment (00:00-23:59)	13:49 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:49
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3192730

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3192730

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 13:17 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 13:17

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

US3192730

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

12:28 (24 HR)

Collection date and time (derived)

13 JAN 2021 12:28

US3192730

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00 - 23:59)	12:21
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Collection Date and Time (derived)	13 JAN 2021 12:21
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US3192730

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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)	12 FEB 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 11:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	102 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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)	12 FEB 2021
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:07
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3192730

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3192730

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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) 12 FEB 2021

What was the treatment time? (00:00-23:59) 11:37 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 11:37

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

What was the frequency of the study treatment dosing? ONCE

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

US3192730

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192730

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:34:28

Generated On: 11 Aug 2021 22:04:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192730

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy) _____

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

Folder OID OLD57

US3192730

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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) _____

US3192730

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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.

US3192730

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3192730

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 01:46:26

Generated On: 11 Aug 2021 22:04:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192730

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

AEID	
Adverse event	WORSENING OF TACHYCARDIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 OCT 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3192730

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

AEID

Adverse event

JOINT PAIN POST INJECTION
"GENERAL"

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

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

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 14:33:15

Generated On: 11 Aug 2021 22:04:44

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Name of Medication ANASTROZOLE

Prophylaxis Yes ☐
No ☒

Indication BREAST CANCER RECURRENCE
PREVENTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2009	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN POST INJECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication JOINT PAIN POST INJECTION

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC INJECTIONS

Dose per administration NA

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

If dose unit is Other, specify NA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		SUBDERMAL
Start date (dd MMM yyyy)		01 FEB 2021
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		01 FEB 2021
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"/>

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC INJECTIONS

Dose per administration NA

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

If dose unit is Other, specify NA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	SUBDERMAL	
Start date (dd MMM yyyy)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	15 OCT 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"/>

US3192730

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 15:19:27

Generated On: 11 Aug 2021 22:04:44

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 11 Aug 2021 22:04:44

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3192730

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 28 Apr 2021 22:35:11

Generated On: 11 Aug 2021 22:04:44

Date of dosing discontinuation (dd MMM yyyy)	06 NOV 2020
--	-------------

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

PATIENT DECLINED DOSE 2
DUE TO WORSENING OF
TACHYCARDIA.

US3192730

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:04:44

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

US3192730 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192730

Form: Participant Creation

Generated On: 11 Aug 2021 22:04:44

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:00:07
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'US3192730'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:33

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Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:11:18
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:18

US3192730

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:11:18
User entered '04 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:35

US3192730

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:11:18
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:18

US3192730

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'SCRN'	System	04 Oct 2020 18:54:18

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:36

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '68'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'YEARS'	System	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '68'	System	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered 'Female (F)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered 'I'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:04:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:17:57
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:35

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:02
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'Oct 2020'	System	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '2020'	System	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:05:58
User closed query 'Per IRB approval Amendment 4 was approved on 1Oct. Please review to confirm if Amendment 4 is the correct protocol version for subject's enrollment. Thanks' (Site from CRA). Query 'Per IRB approval Amendment 4 was approved on 1Oct. Please review to confirm if Amendment 4 is the correct protocol version for subject's enrollment. Thanks' answered with 'updated' (Site from CRA).	(b) (4)	26 Jan 2021 18:05:49
User entered 'Amendment 4 (4)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	25 Nov 2020 20:07:40
User opened query 'Per IRB approval Amendment 4 was approved on 1Oct. Please review to confirm if Amendment 4 is the correct protocol version for subject's enrollment. Thanks' (Site from CRA). User entered 'Amendment 3 (3)'	maggie Tono (b) (4) (b) (4), (b) (6)	25 Nov 2020 20:07:34
	Saysamone Banks (b) (4) (b) (4)	22 Nov 2020 17:22:59
		04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:06
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:07
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:09
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:11
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:45

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:23:14
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:35

US3192730

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:04:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '1'	System	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:24:52
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:04:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:24:55
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:32

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:35
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:37:40
Data point term sent to Coder	System	04 Oct 2020 22:37:04
User entered 'breast cancer'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:37
User entered '31 Jul 2008'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:38
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:40
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:04
User closed query 'Per DM CLR: Please note, the stop date of this MH condition is APR 2009, however, date of surgery (#2 DOUBLE MASTECTOMY) is APR 2010. It does not correspond to the Stop Date of the procedure. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).		24 Dec 2020 04:28:06
User entered 'UN Apr 2010' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	20 Dec 2020 19:31:18
Query 'Per DM CLR: Please note, the stop date of this MH condition is APR 2009, however, date of surgery (#2 DOUBLE MASTECTOMY) is APR 2010. It does not correspond to the Stop Date of the procedure. Review if this should be reconciled. Else, Please clarify dates.' answered with 'data reconciled, should be 2010. updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	20 Dec 2020 19:31:12
User opened query 'Per DM CLR: Please note, the stop date of this MH condition is APR 2009, however, date of surgery (#2 DOUBLE MASTECTOMY) is APR 2010. It does not correspond to the Stop Date of the procedure. Review if this should be reconciled. Else, Please clarify dates.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 04:09:49
User entered 'un Apr 2009'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:42
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jul 2008'	System	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2008'	System	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Apr 2010'	System	20 Dec 2020 19:31:18
User entered 'Apr 2009'	System	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2010'	System	20 Dec 2020 19:31:18
User entered '2009'	System	04 Oct 2020 22:36:57

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User coded data point as SOC: Surgical and medical procedures, HLG: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy bilateral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
Data point term sent to Coder	System	04 Oct 2020 22:38:05
User entered 'double mastectomy'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User entered 'un Apr 2010'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User entered 'un Apr 2010'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:52
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Apr 2010'	System	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2010'	System	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Apr 2010'	System	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2010'	System	04 Oct 2020 22:37:19

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
Data point term sent to Coder	System	04 Oct 2020 22:38:04
User entered 'hysterectomy'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User entered 'un UNK 2000'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User entered 'un UNK 2000'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:28:59
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jan 2000'	System	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2000'	System	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jan 2000'	System	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2000'	System	04 Oct 2020 22:37:38

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:30
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 22:38:41
Data point term sent to Coder	System	04 Oct 2020 22:38:05
User entered 'fibroids'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:32
User entered 'un UNK 1995'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:34
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:35
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:23:54
User closed query 'Per source stop date is 'unk unk 2000'. Please reconcile source and RAVE data. Thanks' (Site from CRA).		02 Feb 2021 23:23:51
Query 'Per source stop date is 'unk unk 2000'. Please reconcile source and RAVE data. Thanks' answered with 'updated to reflect source' (Site from CRA).	Yvonne De Los Reyes (b) (4)	20 Dec 2020 19:33:07
User entered 'UN UNK 2000' reason for change:	Yvonne De Los Reyes	20 Dec 2020 19:32:58
Data Entry Error	(b) (4)	
User opened query 'Per source stop date is 'unk unk 2000'. Please reconcile source and RAVE data. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 17:26:26
User entered 'un UNK 1995'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:26:37
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jan 1995'	System	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '1995'	System	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jan 2000'	System	20 Dec 2020 19:32:58
User entered 'Jan 1995'	System	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2000'	System	20 Dec 2020 19:32:58
User entered '1995'	System	04 Oct 2020 22:37:54

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:54:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:54:26
Data point term sent to Coder	System	06 Nov 2020 23:53:20
User entered 'Tachycardia'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User entered 'I'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:04
User entered '0'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	06 Nov 2020 23:53:13

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 21:46:52
Data point term sent to Coder	System	26 Apr 2021 21:46:09
User entered 'Botox'	(b) (4), (b) (6)	26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'un Jun 2020'		26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '0'		26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'Yes (Y)'		26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered empty.		26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
DataPoint Verified.		30 Apr 2021 16:12:51
Data hard unlocked.		30 Apr 2021 05:13:14
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '0'		26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered 'Jun 2020'	System	26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered '2020'	System	26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:13:29
Data hard unlocked.		30 Apr 2021 05:13:14
Data hard locked.		27 Apr 2021 23:46:15
User entered empty.	System	26 Apr 2021 21:45:50

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.		14 Feb 2021 03:28:01
DataPoint Verified.		22 Nov 2020 17:29:25
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.		14 Feb 2021 03:28:01
DataPoint Verified.		22 Nov 2020 17:29:25
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered '11:00'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '4 Oct 2020 11:00'	System	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered '60' in	Saysamone Banks (b) (4)	04 Oct 2020 22:38:35
DataPoint set to visible.	(b) (4) System	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered '128.8' lb	Saysamone Banks (b) (4)	04 Oct 2020 22:38:35
DataPoint set to visible.	(b) (4) System	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered '25.20712'	System	04 Oct 2020 22:38:35
DataPoint set to visible.	System	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'kg/m2'	System	04 Oct 2020 22:38:35
DataPoint set to visible.	System	04 Oct 2020 18:54:50

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'bpm'	System	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'breaths/min'	System	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'mmHg'	System	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:25
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User entered 'mmHg'	System	04 Oct 2020 22:38:35

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15

US3192730

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15

US3192730

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:42
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:43

US3192730

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:29:42
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:38:43

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered 'Surgically sterile (SURGICALLY STERILE)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered 'un UNK 2000'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:04:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:20
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:39

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
User entered '0'	Saysamone Banks (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered 'I'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
User entered '0'	Saysamone Banks (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:04:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:46:15
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:39
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:14

US3192730

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:49
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:29

US3192730

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:49
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:29

US3192730

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:30:49
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:40:29

US3192730

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'VISIT1'	System	04 Oct 2020 22:40:29

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered '04 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:41

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered '191447'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:41

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Oct 2020 18:02:41

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:01

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:01

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:01

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:01

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:01

US3192730

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:32:47
User entered 'No (N)'	Saysamone Banks (b) (4)	04 Oct 2020 22:41:01
DataPoint set to visible.	(b) (4) System	04 Oct 2020 18:54:45

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User accepted default value 'Pre-Dose (PREDOSE)'	Saysamone Banks (b) (4)	04 Oct 2020 22:39:16
	(b) (4)	

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '11:00'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered '4 Oct 2020 11:00'	System	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '98.0' F	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered 'Oral (Oral)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '101'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'bpm'	System	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '16'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'breaths/min'	System	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '135'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'mmHg'	System	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '85'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'mmHg'	System	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered missing code ND - Not Done.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:39:16

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User accepted default value 'Post-Dose (POSTDOSE)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '12:06'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered '4 Oct 2020 12:06'	System	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '98.5' F	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered 'Oral (Oral)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '84'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'bpm'	System	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '14'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'breaths/min'	System	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '121'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'mmHg'	System	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:37
User entered '77'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'mmHg'	System	04 Oct 2020 22:41:35

US3192730

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:45
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:40

US3192730

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:33:45
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:40

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'MRNA-1273 OR PLACEBO'	System	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered '11:36'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered '4 Oct 2020 11:36'	System	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:27
User entered 'Left Arm (LEFT ARM)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
DataPoint Verified.		22 Nov 2020 17:34:27
User entered 'ONCE'	System	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'INTRAMUSCULAR'	System	04 Oct 2020 18:55:10

US3192730

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:37
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:58

US3192730

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:37
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:58

US3192730

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:37
User entered '11:15'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:41:58

US3192730

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered '4 Oct 2020 11:15'	System	04 Oct 2020 22:41:58

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:49
User entered '4 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Saysamone Banks (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:49
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:49
User entered '11:10'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered '4 Oct 2020 11:10'	System	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Saysamone Banks (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:49
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:49
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered empty.	System	04 Oct 2020 22:42:13

US3192730

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:34:58
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:20

US3192730

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'I'	System	04 Oct 2020 22:42:20

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:09:33', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '87c095a2-2b2c-4f12-818f-e8bc6904ceb0' User entered 'Yes (Y)'	System	04 Oct 2020 19:11:23
	System	04 Oct 2020 19:11:23

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:10:19', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '87c095a2-2b2c-4f12-818f-e8bc6904ceb0' User entered '98.1'	System	04 Oct 2020 19:11:23
	System	04 Oct 2020 19:11:23

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:11:02', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '87c095a2-2b2c-4f12-818f-e8bc6904ceb0' User entered 'No (N)'	System	04 Oct 2020 19:11:23
	System	04 Oct 2020 19:11:23

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:11:21', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '87c095a2-2b2c-4f12-818f-e8bc6904ceb0' User entered '04 Oct 2020 12:11'	System	04 Oct 2020 19:11:23
	System	04 Oct 2020 19:11:23

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 11:56'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 14:26'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, after vaccination (at home)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 15:21'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 2'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 3'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:09', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '03316c2b-c143-4bf1-b93c-4a4e1e5919ba' User entered 'Yes (Y)'	System	06 Oct 2020 21:41:30
	System	06 Oct 2020 21:41:30

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:18', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '03316c2b-c143-4bf1-b93c-4a4e1e5919ba' User entered '97.5'	System	06 Oct 2020 21:41:30
	System	06 Oct 2020 21:41:30

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:22', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '03316c2b-c143-4bf1-b93c-4a4e1e5919ba' User entered 'No (N)'	System	06 Oct 2020 21:41:30
	System	06 Oct 2020 21:41:30

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:28', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '03316c2b-c143-4bf1-b93c-4a4e1e5919ba' User entered '06 Oct 2020 14:41'	System	06 Oct 2020 21:41:30
	System	06 Oct 2020 21:41:30

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 4'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:14:43', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '19497b6f-a31f-40ac-9dc1-502aedic84705' User entered 'Yes (Y)'	System	07 Oct 2020 21:16:05
	System	07 Oct 2020 21:16:05

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:15:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '19497b6f-a31f-40ac-9dc1-502aedic84705' User entered '98.1'	System	07 Oct 2020 21:16:05
	System	07 Oct 2020 21:16:05

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:15:28', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '19497b6f-a31f-40ac-9dc1-502aedic84705'	System	07 Oct 2020 21:16:05
User entered 'No (N)'	System	07 Oct 2020 21:16:05

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:01', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '19497b6f-a31f-40ac-9dc1-502aedc84705' User entered '07 Oct 2020 14:16'	System	07 Oct 2020 21:16:05
	System	07 Oct 2020 21:16:05

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 5'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '86976528-7def-4ab0-b8f5-f5bd81c533c1' User entered 'Yes (Y)'	System	08 Oct 2020 20:50:42
	System	08 Oct 2020 20:50:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:25', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '86976528-7def-4ab0-b8f5-f5bd81c533c1' User entered '98.0'	System	08 Oct 2020 20:50:42
	System	08 Oct 2020 20:50:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:31', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '86976528-7def-4ab0-b8f5-f5bd81c533c1' User entered 'No (N)'	System	08 Oct 2020 20:50:42
	System	08 Oct 2020 20:50:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:37', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '86976528-7def-4ab0-b8f5-f5bd81c533c1' User entered '08 Oct 2020 13:50'	System	08 Oct 2020 20:50:42
	System	08 Oct 2020 20:50:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 6'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:14', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dd4d149d-fbff-41e8-b160-ce11c04255b3' User entered 'Yes (Y)'	System	09 Oct 2020 19:07:53
	System	09 Oct 2020 19:07:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:20', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dd4d149d-fbff-41e8-b160-ce11c04255b3' User entered '97.0'	System	09 Oct 2020 19:07:53
	System	09 Oct 2020 19:07:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:26', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dd4d149d-fbff-41e8-b160-ce11c04255b3'	System	09 Oct 2020 19:07:53
User entered 'No (N)'	System	09 Oct 2020 19:07:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:30', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dd4d149d-fbff-41e8-b160-ce11c04255b3' User entered '09 Oct 2020 12:07'	System	09 Oct 2020 19:07:53
	System	09 Oct 2020 19:07:53

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 7'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:25', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '08cdbc44-1dd5-4f2c-98ef-934f1aefd4c7' User entered 'Yes (Y)'	System	10 Oct 2020 19:05:42
	System	10 Oct 2020 19:05:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:30', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '08cdabc44-1dd5-4f2c-98ef-934f1aefd4c7' User entered '97.5'	System	10 Oct 2020 19:05:42
	System	10 Oct 2020 19:05:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '08cdbc44-1dd5-4f2c-98ef-934f1aefd4c7'	System	10 Oct 2020 19:05:42
User entered 'No (N)'	System	10 Oct 2020 19:05:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:38', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '08cdbc44-1dd5-4f2c-98ef-934f1aefd4c7' User entered '10 Oct 2020 12:05'	System	10 Oct 2020 19:05:42
	System	10 Oct 2020 19:05:42

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '11 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:12:01', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '93b81ecf-f9ae-43e2-9a67-74543ed13e78'	System	04 Oct 2020 19:12:34
User entered 'None (1)'	System	04 Oct 2020 19:12:34

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:12:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '93b81ecf-f9ae-43e2-9a67-74543ed13e78'	System	04 Oct 2020 19:12:34
User entered 'No (N)'	System	04 Oct 2020 19:12:34

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:12:17', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '93b81ecf-f9ae-43e2-9a67-74543ed13e78'	System	04 Oct 2020 19:12:34
User entered 'No (N)'	System	04 Oct 2020 19:12:34

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:12:27', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '93b81ecf-f9ae-43e2-9a67-74543ed13e78'	System	04 Oct 2020 19:12:34
User entered 'None (1)'	System	04 Oct 2020 19:12:34

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:12:32', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '93b81ecf-f9ae-43e2-9a67-74543ed13e78' User entered '04 Oct 2020 12:12'	System	04 Oct 2020 19:12:34
	System	04 Oct 2020 19:12:34

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 11:56'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 14:26'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, after vaccination (at home)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 15:21'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 2'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 3'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:49', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fcc29b58-2a4a-4ba0-97a3-68e247be0de7' User entered 'None (1)'	System	06 Oct 2020 21:42:14
	System	06 Oct 2020 21:42:14

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:41:56', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fcc29b58-2a4a-4ba0-97a3-68e247be0de7' User entered 'No (N)'	System	06 Oct 2020 21:42:14
	System	06 Oct 2020 21:42:14

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fcc29b58-2a4a-4ba0-97a3-68e247be0de7' User entered 'No (N)'	System	06 Oct 2020 21:42:14
	System	06 Oct 2020 21:42:14

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:05', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fcc29b58-2a4a-4ba0-97a3-68e247be0de7' User entered 'None (1)'	System	06 Oct 2020 21:42:14
	System	06 Oct 2020 21:42:14

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:10', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fcc29b58-2a4a-4ba0-97a3-68e247be0de7' User entered '06 Oct 2020 14:42'	System	06 Oct 2020 21:42:14
	System	06 Oct 2020 21:42:14

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 4'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:06', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '36f5d3eb-47ea-41c9-9586-e633a76249e2' User entered 'None (1)'	System	07 Oct 2020 21:16:46
	System	07 Oct 2020 21:16:46

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:17', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '36f5d3eb-47ea-41c9-9586-e633a76249e2' User entered 'No (N)'	System	07 Oct 2020 21:16:46
	System	07 Oct 2020 21:16:46

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:22', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '36f5d3eb-47ea-41c9-9586-e633a76249e2' User entered 'No (N)'	System	07 Oct 2020 21:16:46
	System	07 Oct 2020 21:16:46

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '36f5d3eb-47ea-41c9-9586-e633a76249e2' User entered 'None (1)'	System	07 Oct 2020 21:16:46
	System	07 Oct 2020 21:16:46

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:41', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '36f5d3eb-47ea-41c9-9586-e633a76249e2' User entered '07 Oct 2020 14:16'	System	07 Oct 2020 21:16:46
	System	07 Oct 2020 21:16:46

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 5'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:49', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '4cfd0f96-bab5-4a01-b9ac-5e2d2d78f15e' User entered 'None (1)'	System	08 Oct 2020 20:51:11
	System	08 Oct 2020 20:51:11

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:52', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '4cfd0f96-bab5-4a01-b9ac-5e2d2d78f15e' User entered 'No (N)'	System	08 Oct 2020 20:51:11
	System	08 Oct 2020 20:51:11

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:50:55', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '4cfd0f96-bab5-4a01-b9ac-5e2d2d78f15e' User entered 'No (N)'	System	08 Oct 2020 20:51:11
	System	08 Oct 2020 20:51:11

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '4cfd0f96-bab5-4a01-b9ac-5e2d2d78f15e' User entered 'None (1)'	System	08 Oct 2020 20:51:11
	System	08 Oct 2020 20:51:11

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:06', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '4cfd0f96-bab5-4a01-b9ac-5e2d2d78f15e' User entered '08 Oct 2020 13:51'	System	08 Oct 2020 20:51:11
	System	08 Oct 2020 20:51:11

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 6'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'da72c157-fc48-4279-a2b6-4a3e8ec823f2'	System	09 Oct 2020 19:08:12
User entered 'None (1)'	System	09 Oct 2020 19:08:12

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:38', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'da72c157-fc48-4279-a2b6-4a3e8ec823f2'	System	09 Oct 2020 19:08:12
User entered 'No (N)'	System	09 Oct 2020 19:08:12

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:45', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'da72c157-fc48-4279-a2b6-4a3e8ec823f2'	System	09 Oct 2020 19:08:12
User entered 'No (N)'	System	09 Oct 2020 19:08:12

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:07:59', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'da72c157-fc48-4279-a2b6-4a3e8ec823f2'	System	09 Oct 2020 19:08:12
User entered 'None (1)'	System	09 Oct 2020 19:08:12

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:09', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'da72c157-fc48-4279-a2b6-4a3e8ec823f2'	System	09 Oct 2020 19:08:12
User entered '09 Oct 2020 12:08'	System	09 Oct 2020 19:08:12

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 7'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:42', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '261db2f8-a792-46c2-b89f-a990eb0ac403'	System	10 Oct 2020 19:05:57
User entered 'None (1)'	System	10 Oct 2020 19:05:57

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:45', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '261db2f8-a792-46c2-b89f-a990eb0ac403'	System	10 Oct 2020 19:05:57
User entered 'No (N)'	System	10 Oct 2020 19:05:57

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:47', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '261db2f8-a792-46c2-b89f-a990eb0ac403' User entered 'No (N)'	System	10 Oct 2020 19:05:57
	System	10 Oct 2020 19:05:57

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:52', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '261db2f8-a792-46c2-b89f-a990eb0ac403' User entered 'None (1)'	System	10 Oct 2020 19:05:57
	System	10 Oct 2020 19:05:57

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:55', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '261db2f8-a792-46c2-b89f-a990eb0ac403'	System	10 Oct 2020 19:05:57
User entered '10 Oct 2020 12:05'	System	10 Oct 2020 19:05:57

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '11 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:02', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:11', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:23', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:28', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:31', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'None (0)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:42', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered 'No (N)'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E6432F03-8855-4F01-80E6-458F5F52CB12)', Time: '2020-10-04T12:13:50', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ce7aea3-02f1-48c7-8bb0-b02a42622f22' User entered '04 Oct 2020 12:13'	System	04 Oct 2020 19:13:53
	System	04 Oct 2020 19:13:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 11:56'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 14:26'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 1, after vaccination (at home)'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '04 Oct 2020 15:21'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 2'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 3'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:19', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'None (0)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:24', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'None (0)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:27', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'None (0)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:31', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'None (0)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'None (0)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b'	System	06 Oct 2020 21:43:07
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:42:58', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered 'No (N)'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-06T14:43:05', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '811b7e00-4e7f-4c0a-a1b5-b43dff700f4b' User entered '06 Oct 2020 14:43'	System	06 Oct 2020 21:43:07
	System	06 Oct 2020 21:43:07

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '06 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 4'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:16:55', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:04', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:10', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:16', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered 'None (0)'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:19', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544'	System	07 Oct 2020 21:17:27
User entered 'No (N)'	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-07T14:17:24', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9311b5d9-7ca8-4426-92ba-73ed21a33544' User entered '07 Oct 2020 14:17'	System	07 Oct 2020 21:17:27
	System	07 Oct 2020 21:17:27

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '07 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 5'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:11', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:15', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:18', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:20', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:22', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered 'None (0)'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:27', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc'	System	08 Oct 2020 20:51:39
User entered 'No (N)'	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-08T13:51:35', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'dc8505b6-1d32-444f-abc6-90e5ffdb61bc' User entered '08 Oct 2020 13:51'	System	08 Oct 2020 20:51:39
	System	08 Oct 2020 20:51:39

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '08 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 6'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:17', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:20', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:23', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:25', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:28', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:32', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'None (0)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:36', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered 'No (N)'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-09T12:08:44', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '48af31e9-f033-4706-a207-fbbca9c6631c' User entered '09 Oct 2020 12:08'	System	09 Oct 2020 19:08:47
	System	09 Oct 2020 19:08:47

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '09 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
Data entry locked.	System	04 Oct 2020 18:55:10
User entered 'Day 7'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:05:59', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:01', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:03', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:04', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:06', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:08', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'None (0)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

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)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:12', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered 'No (N)'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-10-10T12:06:15', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c6eb942f-d749-4e30-b2af-964b4bf97d2c' User entered '10 Oct 2020 12:06'	System	10 Oct 2020 19:06:17
	System	10 Oct 2020 19:06:17

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '10 Oct 2020 12:00'	System	04 Oct 2020 18:55:10

US3192730

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:04:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:54:53
User entered '11 Oct 2020 11:59'	System	04 Oct 2020 18:55:10

US3192730

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:52
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	13 Oct 2020 22:42:35

US3192730

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:52
User entered '11 Oct 2020'	Zoe Sesma (b) (4) (b) (4)	13 Oct 2020 22:42:35

US3192730

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:52
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	13 Oct 2020 23:08:36
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Zoe Sesma (b) (4)	13 Oct 2020 22:42:35
	(b) (4)	

US3192730

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:52
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4) (b) (4)	13 Oct 2020 23:08:36
User entered 'pt requested to give us a call back, as she was at work'	Zoe Sesma (b) (4) (b) (4)	13 Oct 2020 22:42:35

US3192730

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:35:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	13 Oct 2020 23:08:39

US3192730

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'I'	System	13 Oct 2020 23:08:39

US3192730

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:08
User entered 'Yes (Y)'		21 Oct 2020 22:40:04

US3192730

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:08
User entered '21 Oct 2020'		21 Oct 2020 22:40:04

US3192730

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:08
User entered 'Contact Made (CONTACT MADE)'		21 Oct 2020 22:40:04

US3192730

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:08
User entered empty.		21 Oct 2020 22:40:04

US3192730

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:22
User entered 'Yes (Y)'		21 Oct 2020 22:40:09

US3192730

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:23:32
User entered 'I'	System	21 Oct 2020 22:40:09

US3192730

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:31
User entered 'Yes (Y)'		27 Oct 2020 22:22:24

US3192730

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:31
User entered '27 Oct 2020'		27 Oct 2020 22:22:24

US3192730

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:31
User entered 'Contact Made (CONTACT MADE)'		27 Oct 2020 22:22:24

US3192730

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:31
User entered empty.		27 Oct 2020 22:22:24

US3192730

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:36:34
User entered 'Yes (Y)'		27 Oct 2020 22:22:28

US3192730

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:48:18
User entered 'I'	System	27 Oct 2020 22:22:28

US3192730

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:22
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:33:47

US3192730

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:22
User entered '6 Nov 2020'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:33:47

US3192730

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[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 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:22
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:33:47

US3192730

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'VISIT2'	System	06 Nov 2020 16:33:47

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '6 Nov 2020'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '08:12'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '6 Nov 2020 08:12'	System	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '98.4' F	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '86'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'bpm'	System	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '14'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'breaths/min'	System	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '115'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'mmHg'	System	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered '72'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'mmHg'	System	06 Nov 2020 16:37:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User accepted default value 'Post-Dose (POSTDOSE)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:37:48
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:37:38

US3192730

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:48:59
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:34:04

US3192730

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:48:59
User entered '6 Nov 2020'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:34:04

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User closed query 'Dosing discontinuation page is blank, please update. Thanks' (Site from CRA).		07 Apr 2021 03:50:52
Query 'Dosing discontinuation page is blank, please update. Thanks' answered with 'dosing discontinuation page has been updated' (Site from CRA).	Saysamone Banks (b) (4)	30 Mar 2021 21:24:39
User opened query 'Dosing discontinuation page is blank, please update. Thanks' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 04:52:38
User closed query 'Please complete Dosing Discontinuation form (under 'end of study'). Thanks' (Site from CRA).		19 Feb 2021 04:52:38
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
Query 'Please complete Dosing Discontinuation form (under 'end of study'). Thanks' answered with 'done' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:44:47
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 17:45:56
User opened query 'Please complete Dosing Discontinuation form (under 'end of study'). Thanks' (Site from CRA).		22 Nov 2020 17:45:18
User entered 'No (N)'	Tianna Young (b) (4)	06 Nov 2020 16:36:34

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
DataPoint Verified.		20 Apr 2021 17:00:33
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
User closed query 'Per CDM: If No, reason not given is recorded as Participant declined due to Adverse Event. However there is no AE recorded for this subject. Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 03:22:44
Query 'Per CDM: If No, reason not given is recorded as Participant declined due to Adverse Event. However there is no AE recorded for this subject. Please review and update the data else clarify. Thank you.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:44:09
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	15 Jan 2021 22:05:10
User entered 'Other (OTHER)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	15 Jan 2021 22:05:10
DataPoint Verified.	(b) (4), (b) (6)	22 Nov 2020 17:59:29
Query 'Per source a reason for the 'no' to 'was study treatment given' is not explicitly provided. Please clarify source and revise data in RAVE as needed. Thanks' canceled (Site from CRA).		22 Nov 2020 17:59:25
User opened query 'Per source a reason for the 'no' to 'was study treatment given' is not explicitly provided. Please clarify source and revise data in RAVE as needed. Thanks' (Site from CRA).		22 Nov 2020 17:47:58
User opened query 'Per CDM: If No, reason not given is recorded as Participant declined due to Adverse Event. However there is no AE recorded for this subject. Please review and update the data else clarify. Thank you.' (Site from DM).		12 Nov 2020 07:57:25
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:36:34

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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)	27 Apr 2021 21:44:27
DataPoint Verified.		20 Apr 2021 17:00:43
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Un-verified.	(b) (4)	
	Yvonne De Los Reyes	15 Jan 2021 22:05:10
	(b) (4)	
User entered 'patient declined Dose 2 due to hx of tachycardia.' reason for change: Data Entry Error	Yvonne De Los Reyes	15 Jan 2021 22:05:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Nov 2020 17:49:16
User entered empty.	Tianna Young (b) (4)	06 Nov 2020 16:36:34
	(b) (4)	

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:49:15
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:49:13
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:49:11
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
DataPoint Verified.		22 Nov 2020 17:49:10
User entered empty.	System	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:36:34

US3192730

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:20
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:20
User entered '6 Nov 2020'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:20
User entered '08:57'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '6 Nov 2020 08:57'	System	06 Nov 2020 16:35:32

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:26
User entered '6 Nov 2020'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:26
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:26
User entered '09:02'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '6 Nov 2020 09:02'	System	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:26
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:26
User entered empty.	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered empty.	System	06 Nov 2020 16:35:52

US3192730

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:50:30
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	06 Nov 2020 16:35:58

US3192730

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '1'	System	06 Nov 2020 16:35:58

US3192730

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:53:48
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	17 Nov 2020 15:48:44

US3192730

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:53:48
User entered '13 Nov 2020'	Zoe Sesma (b) (4) (b) (4)	17 Nov 2020 15:48:44

US3192730

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:53:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	Zoe Sesma (b) (4) (b) (4)	17 Nov 2020 15:48:44

US3192730

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:53:48
User entered '-LVM asking patient to give us a call back (Nov 13, 20) -LVM 2nd attempt (Nov 16, 20) -LVM 3rd attempt (Nov 16, 20)'	Zoe Sesma (b) (4) (b) (4)	17 Nov 2020 15:48:44

US3192730

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Nov 2020 17:53:52
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	17 Nov 2020 15:48:47

US3192730

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'I'	System	17 Nov 2020 15:48:47

US3192730

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:40
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	24 Nov 2020 15:39:58

US3192730

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:40
User entered '23 Nov 2020'	Amanda Hermosillo (b) (4)	24 Nov 2020 15:39:58

US3192730

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:40
User entered 'Contact Made (CONTACT MADE)'	Amanda Hermosillo (b) (4)	24 Nov 2020 15:39:58

US3192730

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:40
User entered empty.	Amanda Hermosillo (b) (4)	24 Nov 2020 15:39:58

US3192730

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:43
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	24 Nov 2020 15:40:05

US3192730

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'I'	System	24 Nov 2020 15:40:05

US3192730

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:49
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:42

US3192730

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:49
User entered '30 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:42

US3192730

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:49
User entered 'Contact Made (CONTACT MADE)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:42

US3192730

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:49
User entered empty.	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:42

US3192730

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:24:52
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:46

US3192730

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'I'	System	07 Dec 2020 23:30:46

US3192730

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:08
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:55

US3192730

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:08
User entered '7 Dec 2020'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:55

US3192730

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[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 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:08
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:30:55

US3192730

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'VISIT3'	System	07 Dec 2020 23:30:55

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '7 Dec 2020'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '11:12'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '7 Dec 2020 11:12'	System	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '97.7' F	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered 'Oral (Oral)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered empty.	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '88'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'bpm'	System	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '14'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'breaths/min'	System	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '121'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'mmHg'	System	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:19
User entered '74'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'mmHg'	System	07 Dec 2020 23:31:25

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27

US3192730

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27

US3192730

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:23
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:38

US3192730

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:23
User entered '7 Dec 2020'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:38

US3192730

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:33
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:48

US3192730

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:33
User entered '7 Dec 2020'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:48

US3192730

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:33
User entered '11:50'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:48

US3192730

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered '7 Dec 2020 11:50'	System	07 Dec 2020 23:31:48

US3192730

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:28:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:37
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	07 Dec 2020 23:31:52

US3192730

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'I'	System	07 Dec 2020 23:31:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Dec 2020 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Dec 2020 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-11T12:55:11', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7f704048-5cfd-4554-a9db-416fcecc7463'	System	11 Dec 2020 19:55:30
User entered 'No (N)'	System	11 Dec 2020 19:55:30

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-11T12:55:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7f704048-5cfd-4554-a9db-416fcecc7463'	System	11 Dec 2020 19:55:30
User entered 'No (N)'	System	11 Dec 2020 19:55:30

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-11T12:55:26', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7f704048-5cfd-4554-a9db-416fcecc7463' User entered '11 Dec 2020 12:55:26'	System	11 Dec 2020 19:55:30
	System	11 Dec 2020 19:55:30

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Dec 2020 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Dec 2020 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-15T06:16:12', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '10bbdf5e-2f68-4f38-a8f4-d611997b798f' User entered 'No (N)'	System	15 Dec 2020 13:16:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-15T06:16:22', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '10bbdf5e-2f68-4f38-a8f4-d611997b798f' User entered 'No (N)'	System	15 Dec 2020 13:16:52
	System	15 Dec 2020 13:16:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-15T06:16:50', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '10bbdf5e-2f68-4f38-a8f4-d611997b798f' User entered '15 Dec 2020 06:16:50'	System	15 Dec 2020 13:16:52
	System	15 Dec 2020 13:16:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Dec 2020 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Dec 2020 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-22T06:23:35', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '595876d4-2f13-44d2-8fbf-3a5bb3fb63d9' User entered 'No (N)'	System	22 Dec 2020 13:24:07
	System	22 Dec 2020 13:24:07

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-22T06:23:40', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '595876d4-2f13-44d2-8fbf-3a5bb3fb63d9' User entered 'No (N)'	System	22 Dec 2020 13:24:07
	System	22 Dec 2020 13:24:07

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-22T06:24:02', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '595876d4-2f13-44d2-8fbf-3a5bb3fb63d9' User entered '22 Dec 2020 06:24:02'	System	22 Dec 2020 13:24:07
	System	22 Dec 2020 13:24:07

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Dec 2020 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Dec 2020 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-29T05:55:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '6d399e8d-0130-4ad1-b092-351d4564cc1b' User entered 'No (N)'	System	29 Dec 2020 12:55:32

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-29T05:55:09', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '6d399e8d-0130-4ad1-b092-351d4564cc1b'	System	29 Dec 2020 12:55:32
User entered 'No (N)'	System	29 Dec 2020 12:55:32

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2020-12-29T05:55:27', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '6d399e8d-0130-4ad1-b092-351d4564cc1b' User entered '29 Dec 2020 05:55:27'	System	29 Dec 2020 12:55:32
	System	29 Dec 2020 12:55:32

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Dec 2020 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Jan 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-05T08:18:49', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '49251316-4a7f-4adf-9b65-3c8acd9c8a04' User entered 'No (N)'	System	05 Jan 2021 15:19:09

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-05T08:18:52', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '49251316-4a7f-4adf-9b65-3c8acd9c8a04'	System	05 Jan 2021 15:19:09
User entered 'No (N)'	System	05 Jan 2021 15:19:09

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-05T08:19:07', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '49251316-4a7f-4adf-9b65-3c8acd9c8a04'	System	05 Jan 2021 15:19:09
User entered '05 Jan 2021 08:19:07'	System	05 Jan 2021 15:19:09

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Jan 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Jan 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-12T06:51:32', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'bf757ebd-9e54-4515-a67c-463d809582a0' User entered 'No (N)'	System	12 Jan 2021 13:51:50
	System	12 Jan 2021 13:51:50

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-12T06:51:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'bf757ebd-9e54-4515-a67c-463d809582a0'	System	12 Jan 2021 13:51:50
User entered 'No (N)'	System	12 Jan 2021 13:51:50

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-12T06:51:47', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'bf757ebd-9e54-4515-a67c-463d809582a0' User entered '12 Jan 2021 06:51:47'	System	12 Jan 2021 13:51:50
	System	12 Jan 2021 13:51:50

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Jan 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Jan 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-19T06:22:34', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e4d55b0e-6b33-420a-ae28-ef4a05a97ede' User entered 'No (N)'	System	23 Jan 2021 17:06:08
	System	23 Jan 2021 17:06:08

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-19T06:22:36', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e4d55b0e-6b33-420a-ae28-ef4a05a97ede' User entered 'No (N)'	System	23 Jan 2021 17:06:08

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-19T06:22:45', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e4d55b0e-6b33-420a-ae28-ef4a05a97ede' User entered '19 Jan 2021 06:22:45'	System	23 Jan 2021 17:06:08
	System	23 Jan 2021 17:06:08

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Jan 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Jan 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-28T17:52:51', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '62afbbfa-3b5e-42cf-a1e2-69992d3580e0' User entered 'No (N)'	System	29 Jan 2021 00:53:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-28T17:52:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '62afbbfa-3b5e-42cf-a1e2-69992d3580e0'	System	29 Jan 2021 00:53:01
User entered 'No (N)'	System	29 Jan 2021 00:53:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-01-28T17:52:58', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '62afbbfa-3b5e-42cf-a1e2-69992d3580e0' User entered '28 Jan 2021 17:52:58'	System	29 Jan 2021 00:53:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Jan 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Jan 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-02T11:13:44', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f39d70e2-3902-4168-9db9-71c857cf1f8c' User entered 'No (N)'	System	02 Feb 2021 18:13:55
	System	02 Feb 2021 18:13:55

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-02T11:13:46', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f39d70e2-3902-4168-9db9-71c857cf1f8c'	System	02 Feb 2021 18:13:55
User entered 'No (N)'	System	02 Feb 2021 18:13:55

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-02T11:13:49', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f39d70e2-3902-4168-9db9-71c857cf1f8c' User entered '02 Feb 2021 11:13:49'	System	02 Feb 2021 18:13:55
	System	02 Feb 2021 18:13:55

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Feb 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Feb 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-11T12:04:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc96b818-abbe-48c6-afda-bf7c615cac5b' User entered 'No (N)'	System	11 Feb 2021 19:04:24
	System	11 Feb 2021 19:04:24

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-11T12:04:03', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc96b818-abbe-48c6-afda-bf7c615cac5b' User entered 'No (N)'	System	11 Feb 2021 19:04:24

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-11T12:04:06', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc96b818-abbe-48c6-afda-bf7c615cac5b' User entered '11 Feb 2021 12:04:06'	System	11 Feb 2021 19:04:24
	System	11 Feb 2021 19:04:24

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Feb 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Feb 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:05:01', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678' User entered 'Yes (Y)'	System	16 Feb 2021 07:10:14
	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:05:19', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered 'No (N)'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:05:55', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678' User entered 'Yes (Y)'	System	16 Feb 2021 07:10:14
	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '1'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '1'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '1'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '1'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '1'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:08:54', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '0'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:09:01', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:09:13', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered 'No (N)'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-16T00:10:03', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'a1835f96-1d36-4b8c-8b96-63fbff971678'	System	16 Feb 2021 07:10:14
User entered '16 Feb 2021 00:10:03'	System	16 Feb 2021 07:10:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Feb 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Feb 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-23T06:11:28', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f57dd266-8e31-4fee-be6e-b2e4919a8d61' User entered 'No (N)'	System	23 Feb 2021 13:12:03
	System	23 Feb 2021 13:12:03

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-23T06:11:42', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f57dd266-8e31-4fee-be6e-b2e4919a8d61' User entered 'No (N)'	System	23 Feb 2021 13:12:03

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-02-23T06:11:56', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'f57dd266-8e31-4fee-be6e-b2e4919a8d61' User entered '23 Feb 2021 06:11:56'	System	23 Feb 2021 13:12:03
	System	23 Feb 2021 13:12:03

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Feb 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Feb 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:58:34-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc7cc5ad-8654-46db-9c0d-c10285685ed8'	System	02 Mar 2021 13:58:52
User entered 'No (N)'	System	02 Mar 2021 13:58:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:58:42-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc7cc5ad-8654-46db-9c0d-c10285685ed8'	System	02 Mar 2021 13:58:52
User entered 'No (N)'	System	02 Mar 2021 13:58:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:58:50-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'fc7cc5ad-8654-46db-9c0d-c10285685ed8'	System	02 Mar 2021 13:58:52
User entered '02 Mar 2021 06:58:50'	System	02 Mar 2021 13:58:52

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Mar 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Mar 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-11T12:00:29-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9e11965e-0120-4981-9edf-ea2b27f9a4dd'	System	11 Mar 2021 19:00:58
User entered 'No (N)'	System	11 Mar 2021 19:00:58

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-11T12:00:36-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9e11965e-0120-4981-9edf-ea2b27f9a4dd'	System	11 Mar 2021 19:00:58
User entered 'No (N)'	System	11 Mar 2021 19:00:58

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-11T12:00:45-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '9e11965e-0120-4981-9edf-ea2b27f9a4dd' User entered '11 Mar 2021 12:00:45'	System	11 Mar 2021 19:00:58
	System	11 Mar 2021 19:00:58

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Mar 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Mar 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-19T23:20:24-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '8355d8ac-c749-421d-bb0e-8840965a5171'	System	20 Mar 2021 06:20:35
User entered 'No (N)'	System	20 Mar 2021 06:20:35

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-19T23:20:27-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '8355d8ac-c749-421d-bb0e-8840965a5171'	System	20 Mar 2021 06:20:35
User entered 'No (N)'	System	20 Mar 2021 06:20:35

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-19T23:20:30-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '8355d8ac-c749-421d-bb0e-8840965a5171'	System	20 Mar 2021 06:20:35
User entered '19 Mar 2021 23:20:30'	System	20 Mar 2021 06:20:35

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Mar 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Mar 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-26T18:14:39-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '34e45145-caaa-4802-9045-c2f93afcd7ef' User entered 'No (N)'	System	27 Mar 2021 01:18:49
	System	27 Mar 2021 01:18:49

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-26T18:14:41-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '34e45145-caaa-4802-9045-c2f93afcd7ef' User entered 'No (N)'	System	27 Mar 2021 01:18:49
	System	27 Mar 2021 01:18:49

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-26T18:14:44-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '34e45145-caaa-4802-9045-c2f93afcd7ef' User entered '26 Mar 2021 18:14:44'	System	27 Mar 2021 01:18:49
	System	27 Mar 2021 01:18:49

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Mar 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Mar 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-01T12:20:50-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7ef013cb-3237-4cb4-b503-cbc481bdf28c'	System	01 Apr 2021 19:21:01
User entered 'No (N)'	System	01 Apr 2021 19:21:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-01T12:20:52-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7ef013cb-3237-4cb4-b503-cbc481bdf28c'	System	01 Apr 2021 19:21:01
User entered 'No (N)'	System	01 Apr 2021 19:21:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-01T12:20:55-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7ef013cb-3237-4cb4-b503-cbc481bdf28c'	System	01 Apr 2021 19:21:01
User entered '01 Apr 2021 12:20:55'	System	01 Apr 2021 19:21:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Mar 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 Apr 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-09T18:06:16-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ed654c7-2155-4ffe-bd60-457ee3049d20'	System	10 Apr 2021 01:11:27
User entered 'No (N)'	System	10 Apr 2021 01:11:27

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-09T18:06:18-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ed654c7-2155-4ffe-bd60-457ee3049d20'	System	10 Apr 2021 01:11:27
User entered 'No (N)'	System	10 Apr 2021 01:11:27

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-09T18:06:26-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '3ed654c7-2155-4ffe-bd60-457ee3049d20'	System	10 Apr 2021 01:11:27
User entered '09 Apr 2021 18:06:26'	System	10 Apr 2021 01:11:27

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Apr 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 Apr 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-13T13:31:44-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e0115187-380b-4315-9e95-7859d2b57a85'	System	13 Apr 2021 20:32:01
User entered 'No (N)'	System	13 Apr 2021 20:32:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-13T13:31:50-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e0115187-380b-4315-9e95-7859d2b57a85'	System	13 Apr 2021 20:32:01
User entered 'No (N)'	System	13 Apr 2021 20:32:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-13T13:31:55-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'e0115187-380b-4315-9e95-7859d2b57a85'	System	13 Apr 2021 20:32:01
User entered '13 Apr 2021 13:31:55'	System	13 Apr 2021 20:32:01

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Apr 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '17 Apr 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-20T09:49:20-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '0a7134b1-a8c7-4198-840a-c994110fe0f4'	System	20 Apr 2021 16:49:40
User entered 'No (N)'	System	20 Apr 2021 16:49:40

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-20T09:49:22-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '0a7134b1-a8c7-4198-840a-c994110fe0f4'	System	20 Apr 2021 16:49:40
User entered 'No (N)'	System	20 Apr 2021 16:49:40

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-20T09:49:32-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '0a7134b1-a8c7-4198-840a-c994110fe0f4' User entered '20 Apr 2021 09:49:32'	System	20 Apr 2021 16:49:40
	System	20 Apr 2021 16:49:40

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Apr 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '24 Apr 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-27T04:14:22-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c66f04a7-ab4d-4f8a-8883-570f8dd55978'	System	28 Apr 2021 22:46:14
User entered 'No (N)'	System	28 Apr 2021 22:46:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

Have you been exposed to someone with 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 (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-27T04:14:33-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c66f04a7-ab4d-4f8a-8883-570f8dd55978'	System	28 Apr 2021 22:46:14
User entered 'No (N)'	System	28 Apr 2021 22:46:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-04-27T04:14:42-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: 'c66f04a7-ab4d-4f8a-8883-570f8dd55978'	System	28 Apr 2021 22:46:14
User entered '27 Apr 2021 04:14:42'	System	28 Apr 2021 22:46:14

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Apr 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 May 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 May 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 May 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 May 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 May 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 May 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 May 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 May 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 May 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Jun 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Jun 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Jun 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Jun 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Jun 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Jun 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Jun 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Jun 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Jun 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 Jul 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Jul 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 Jul 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Jul 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '17 Jul 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Jul 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '24 Jul 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Jul 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '31 Jul 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 Aug 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '07 Aug 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 Aug 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '14 Aug 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '17 Aug 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '21 Aug 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '24 Aug 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '28 Aug 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '31 Aug 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 Sep 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '07 Sep 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 Sep 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '14 Sep 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 Sep 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '21 Sep 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 Sep 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '28 Sep 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Oct 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Oct 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Oct 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Oct 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Oct 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Oct 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Oct 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Oct 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Oct 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Nov 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Nov 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Nov 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Nov 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Nov 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Nov 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Nov 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Nov 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Nov 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 Dec 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '07 Dec 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 Dec 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '14 Dec 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 Dec 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '21 Dec 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 Dec 2021 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '28 Dec 2021 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Jan 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 Jan 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Jan 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 Jan 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Jan 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 Jan 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Jan 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 Jan 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Jan 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Feb 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Feb 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Feb 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Feb 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Feb 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Feb 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Feb 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Feb 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Mar 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Mar 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Mar 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Mar 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Mar 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Mar 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Mar 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Mar 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Mar 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Apr 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Apr 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Apr 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Apr 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Apr 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Apr 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Apr 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Apr 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Apr 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 May 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '07 May 2022 23:59'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 May 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '14 May 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '17 May 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '21 May 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '24 May 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '28 May 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '31 May 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 Jun 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '07 Jun 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 Jun 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '14 Jun 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 Jun 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '21 Jun 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 Jun 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '28 Jun 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Jul 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Jul 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Jul 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Jul 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Jul 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Jul 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Jul 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Jul 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Jul 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '02 Aug 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Aug 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '09 Aug 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Aug 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:40:36

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '16 Aug 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Aug 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '23 Aug 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Aug 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '30 Aug 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 Sep 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Sep 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 Sep 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '13 Sep 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '17 Sep 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '20 Sep 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '24 Sep 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '27 Sep 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Oct 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '04 Oct 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Oct 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '11 Oct 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Oct 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '18 Oct 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Oct 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '25 Oct 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Oct 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '01 Nov 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '05 Nov 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '08 Nov 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '12 Nov 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '15 Nov 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '19 Nov 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '22 Nov 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '26 Nov 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '29 Nov 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '03 Dec 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '06 Dec 2022 00:01'	System	20 Nov 2020 11:40:36

US3192730

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:04:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:40:36
Amendment Manager: User entered '10 Dec 2022 23:59'	System	20 Nov 2020 11:40:36

US3192730

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:04:44

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:59:10-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7803aeb3-b569-4b07-9bea-6fdce07c7b30'	System	11 Mar 2021 19:00:32
User entered 'Yes (Y)'	System	11 Mar 2021 19:00:32

US3192730

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:04:44

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:59:29-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7803aeb3-b569-4b07-9bea-6fdce07c7b30'	System	11 Mar 2021 19:00:32
User entered 'No (N)'	System	11 Mar 2021 19:00:32

US3192730

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:04:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:28:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (279447FB-38C4-4794-815C-8742AFE94765)', Time: '2021-03-02T06:59:41-07:00', User OID: 'PatientReportedOutcome (US3192730)', ODM File OID: '7803aeb3-b569-4b07-9bea-6fdce07c7b30' User entered '02 Mar 2021 06:59:41'	System	11 Mar 2021 19:00:32
	System	11 Mar 2021 19:00:32

US3192730

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:36:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:47
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 22:03:15

US3192730

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:36:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:47
User entered '4 Jan 2021'	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 22:03:15

US3192730

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:36:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:47
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 22:03:15

US3192730

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:36:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:47
User entered empty.	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 22:03:15

US3192730

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:36:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:25:50
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	07 Jan 2021 22:03:17

US3192730

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:44:27
User entered 'I'	System	07 Jan 2021 22:03:17

US3192730

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
DataPoint Verified.		20 Apr 2021 00:28:56
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'No (N)'	(b) (4)	
	Damaris Atondo (b) (4)	26 Mar 2021 23:47:31
	(b) (4)	

US3192730

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
DataPoint Verified.		20 Apr 2021 00:28:56
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	26 Mar 2021 23:47:31

US3192730

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
DataPoint Verified.		20 Apr 2021 00:28:56
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	26 Mar 2021 23:47:31
	(b) (4)	

US3192730

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
DataPoint Verified.		20 Apr 2021 00:28:56
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	26 Mar 2021 23:47:31

US3192730

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
DataPoint Verified.		20 Apr 2021 00:29:07
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	13 Mar 2021 21:41:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 15:08:13
Query 'Data is required. Please complete.' answered with 'inadvertently entered' (Site from System).	Yvonne De Los Reyes	21 Jan 2021 22:26:26
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 22:26:17
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes	21 Jan 2021 22:26:17
	(b) (4)	
User entered 'Yes (Y)'	Yvonne De Los Reyes	21 Jan 2021 22:26:08
	(b) (4)	

US3192730

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:46:04
User entered '1'	System	13 Mar 2021 21:41:49
User entered empty.	System	21 Jan 2021 22:26:17
User entered '1'	System	21 Jan 2021 22:26:08

US3192730

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
DataPoint Verified.		20 Apr 2021 00:29:17
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4)	
	Damaris Atondo (b) (4)	13 Mar 2021 21:42:00
	(b) (4)	

US3192730

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
DataPoint Verified.		20 Apr 2021 00:29:17
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '8 Mar 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 21:42:00

US3192730

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
DataPoint Verified.		20 Apr 2021 00:29:17
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 21:42:00

US3192730

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
DataPoint Verified.		20 Apr 2021 00:29:17
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 21:42:00

US3192730

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
DataPoint Verified.		20 Apr 2021 00:31:06
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 21:42:04

US3192730

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:56:20
User entered 'I'	System	13 Mar 2021 21:42:04

US3192730

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:22
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	08 Apr 2021 17:25:21

US3192730

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:22
	(b) (4)	
User entered '8 Apr 2021'	Damaris Atondo (b) (4)	08 Apr 2021 17:25:21
	(b) (4)	

US3192730

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4)	08 Apr 2021 17:25:21
	(b) (4)	

US3192730

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:22
User entered empty.	(b) (4) Damaris Atondo (b) (4)	08 Apr 2021 17:25:21
	(b) (4)	

US3192730

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:22
	(b) (4)	
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	08 Apr 2021 17:25:24
	(b) (4)	

US3192730

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:25:24

US3192730

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:26:33

US3192730

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:26:33

US3192730

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:26:33

US3192730

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 15:26:33

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '08:12'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User entered '23 Apr 2021 08:12'	System	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '12'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '127'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '75'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Apr 2021 15:28:32

US3192730

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:37

US3192730

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:37

US3192730

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:53

US3192730

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:53

US3192730

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered '08:20'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:28:53

US3192730

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User entered '23 Apr 2021 08:20'	System	23 Apr 2021 15:28:53

US3192730

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	25 Apr 2021 17:54:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:29:03

US3192730

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:29:03

US3192730

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:31:33
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:29
	(b) (4)	

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:31:33
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:29
	(b) (4)	

US3192730

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:31:33
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Clinic (Clinic)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:40:29

US3192730

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

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 21:40:29

US3192730

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:33:57
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:43
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:22:41

US3192730

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:33:55
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:13:25
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'updated' (Site from System).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:50:24
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	13 Jan 2021 21:40:43
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:40:43

US3192730

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:22:41

US3192730

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:33:54
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:43
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:33:53
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Placebo (Placebo)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:40:43

US3192730

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:33:52
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	
User entered 'Placebo (Placebo)'	System	20 Jan 2021 15:48:56
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:43
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User signature succeeded.	John McGettigan (b) (4)	23 Apr 2021 14:26:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:41:36
User closed query 'Per IRT output in source subject did not receive the second injection (ie, neither mRNA or Placebo.) Please select 'not administered' if this is applicable. Thanks' (Site from CRA).		20 Apr 2021 16:41:34
Query 'Per IRT output in source subject did not receive the second injection (ie, neither mRNA or Placebo.) Please select 'not administered' if this is applicable. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4) (b) (4)	20 Apr 2021 15:48:43
Signature has been broken.	maggie Tono (b) (4) (b) (4)	20 Apr 2021 15:48:25
User entered 'Not Administered (NA)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	20 Apr 2021 15:48:25
User opened query 'Per IRT output in source subject did not receive the second injection (ie, neither mRNA or Placebo.) Please select 'not administered' if this is applicable. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 00:33:49
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 14:34:28
User closed query 'Per CDM Review: Please provide a response. If not Not Administered, please select Not Administered.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:03:46
Query 'Per CDM Review: Please provide a response. If not Not Administered, please select Not Administered.' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	30 Mar 2021 14:51:08
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	30 Mar 2021 14:51:02
User opened query 'Per CDM Review: Please provide a response. If not Not Administered, please select Not Administered.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:22:51
User entered empty.	Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:40:43

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:34:02
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:40:43
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '1'	System	30 Mar 2021 14:51:02
User entered empty.	System	13 Jan 2021 21:40:43

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

Form: Unblinding

Generated On: 11 Aug 2021 22:04:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'I'	System	30 Mar 2021 14:51:02
User entered empty.	System	13 Jan 2021 21:40:43

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '60' in reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
	(b) (4)	
User entered empty.	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '127.4' lb reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '24.93313'	System	30 Mar 2021 18:19:54
User entered empty.	System	30 Mar 2021 18:18:28
DataPoint set to visible.	System	30 Mar 2021 14:51:02

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '60' in reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
	(b) (4)	
User entered empty.	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '127.4' lb reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '24.93313'	System	30 Mar 2021 18:19:54
User entered empty.	System	30 Mar 2021 18:18:28
DataPoint set to visible.	System	30 Mar 2021 14:51:02

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User accepted default value 'Pre-Dose (PREDOSE)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13 Jan 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '12:00'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '13 Jan 2021 12:00'	System	30 Mar 2021 18:18:28

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '97.6' F	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Oral (Oral)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '80'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'bpm'	System	30 Mar 2021 18:18:28

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '12'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'breaths/min'	System	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '134'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'mmHg'	System	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:37
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '84'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'mmHg'	System	30 Mar 2021 18:18:28

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:47
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '60' in reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
	(b) (4)	
User entered empty.	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '127.4' lb reason for change: Data Entry Error	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:54
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:18:28
	(b) (4)	

US3192730

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:04:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '24.93313'	System	30 Mar 2021 18:19:54
User entered empty.	System	30 Mar 2021 18:18:28
DataPoint set to visible.	System	30 Mar 2021 14:51:02

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User accepted default value 'Post-Dose (POSTDOSE)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13 Jan 2021'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:16
	(b) (4)	

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '13:49'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '13 Jan 2021 13:49'	System	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '97.7' F	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Oral (Oral)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:19:16
	(b) (4)	

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '82'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'bpm'	System	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '14'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'breaths/min'	System	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '117'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'mmHg'	System	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:35:42
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '85'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:19:16

US3192730

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'mmHg'	System	30 Mar 2021 18:19:16

US3192730

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:22
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:20

US3192730

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:22
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '13 Jan 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:20

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:21:41
	(b) (4)	

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'mRNA-1273'	System	30 Mar 2021 18:21:41
DataPoint set to visible.	System	30 Mar 2021 14:51:02

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '13 Jan 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '13:17'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '13 Jan 2021 13:17'	System	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:36
User entered 'ONCE'	System	30 Mar 2021 18:21:41

US3192730

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

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 18:21:41

US3192730

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:41:00

US3192730

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '13 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:41:00
	(b) (4)	

US3192730

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12:28'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:41:00

US3192730

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '13 Jan 2021 12:28'	System	13 Jan 2021 21:41:00

US3192730

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:50
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:41:10

US3192730

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:50
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '13 Jan 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	13 Jan 2021 21:41:10

US3192730

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:50
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12:21'	(b) (4)	
	Saysamone Banks (b) (4)	13 Jan 2021 21:41:10
	(b) (4)	

US3192730

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered '13 Jan 2021 12:21'	System	13 Jan 2021 21:41:10

US3192730

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

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
DataPoint Verified.		20 Apr 2021 00:36:51
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:16:34

US3192730

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

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:27
User entered 'I'	System	30 Mar 2021 18:16:34

US3192730

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
DataPoint Verified.		20 Apr 2021 00:37:14
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:22:55

US3192730

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
DataPoint Verified.		20 Apr 2021 00:37:14
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '21 Jan 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:22:55

US3192730

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
DataPoint Verified.		20 Apr 2021 00:37:14
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:22:55

US3192730

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
DataPoint Verified.		20 Apr 2021 00:37:14
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:22:55

US3192730

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
DataPoint Verified.		20 Apr 2021 00:37:26
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:23:01

US3192730

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
User entered 'I'	System	30 Mar 2021 18:23:01

US3192730

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:58:46
User entered 'I'	System	30 Mar 2021 18:23:01
DataPoint set to visible.	System	30 Mar 2021 18:23:01

US3192730

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:37:58
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:23:38

US3192730

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:37:58
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12 Feb 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:23:38

US3192730

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:37:58
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Clinic (Clinic)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:23:38

US3192730

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'OLD29'	System	30 Mar 2021 18:23:38

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User accepted default value 'Pre-Dose (PREDOSE)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12 Feb 2021'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:25:25
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '11:20'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:25:25
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered '12 Feb 2021 11:20'	System	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '98.2' F	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Oral (Oral)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:25:25
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '102'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:25:25
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'bpm'	System	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'breaths/min'	System	30 Mar 2021 18:25:25

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '115'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:25:25
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'mmHg'	System	30 Mar 2021 18:25:25

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:35
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '82'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'mmHg'	System	30 Mar 2021 18:25:25

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User accepted default value 'Post-Dose (POSTDOSE)'	Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12 Feb 2021'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:26:55
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12:07'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:26:55
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered '12 Feb 2021 12:07'	System	30 Mar 2021 18:26:55

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '98.8' F	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Oral (Oral)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:26:55
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '94'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'bpm'	System	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'breaths/min'	System	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '126'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:26:55
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'mmHg'	System	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:41
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '76'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'mmHg'	System	30 Mar 2021 18:26:55

US3192730

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:55
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:27:08

US3192730

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:38:55
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12 Feb 2021'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:27:08
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:27:27
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'mRNA-1273'	System	30 Mar 2021 18:27:27
DataPoint set to visible.	System	30 Mar 2021 18:23:01

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '12 Feb 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '11:37'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:27:27
	(b) (4)	

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered '12 Feb 2021 11:37'	System	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Left Arm (LEFT ARM)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:05
User entered 'ONCE'	System	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:04:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 18:27:27

US3192730

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
DataPoint Verified.		20 Apr 2021 00:39:08
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'Yes (Y)'	(b) (4)	
	Damaris Atondo (b) (4)	30 Mar 2021 18:27:35
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:52:24
User entered 'I'	System	30 Mar 2021 18:27:35

US3192730

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
DataPoint Verified.		20 Apr 2021 00:39:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:28:16

US3192730

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
DataPoint Verified.		20 Apr 2021 00:39:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered '20 Feb 2021'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:28:16

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
DataPoint Verified.		20 Apr 2021 00:39:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:28:16

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:04:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
DataPoint Verified.		20 Apr 2021 00:39:36
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered empty.	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:28:16

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
DataPoint Verified.		20 Apr 2021 00:39:38
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:34:28
User entered 'Yes (Y)'	(b) (4) Damaris Atondo (b) (4) (b) (4)	30 Mar 2021 18:28:22

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:04:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:33:12
User entered 'I'	System	30 Mar 2021 18:28:22

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	31 Mar 2021 18:22:15
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:15
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:15
	(b) (4)	

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Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:04:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	31 Mar 2021 18:22:15

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered empty.	(b) (4) Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:21

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:21
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:04:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:21

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	31 Mar 2021 18:22:25
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:04:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:25
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	31 Mar 2021 18:22:31
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:31
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	31 Mar 2021 18:22:31
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 18:22:31

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:04:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:54:09
DataPoint Verified.		20 Apr 2021 16:54:15
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User closed query 'Please enter adverse event noted in source. Also confirm if event name is 'worsening tachycardia' since subject already has a baseline condition of 'tachycardia'. Thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 03:48:14
Query 'Please enter adverse event noted in source. Also confirm if event name is 'worsening tachycardia' since subject already has a baseline condition of 'tachycardia'. Thanks' answered with 'updated' (Site from CRA).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:45:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:45:22
User opened query 'Please enter adverse event noted in source. Also confirm if event name is 'worsening tachycardia' since subject already has a baseline condition of 'tachycardia'. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 18:02:29
Query 'Please have a medical provider consider if subject reporting 'experienced episodes of tachycardia since her injection' is an adverse event. Thanks' canceled (Site from CRA).		22 Nov 2020 18:01:33
User opened query 'Please have a medical provider consider if subject reporting 'experienced episodes of tachycardia since her injection' is an adverse event. Thanks' (Site from CRA).		22 Nov 2020 17:43:56
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	06 Oct 2020 15:08:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 19:14:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Jan 2021 19:14:34
Data point term sent to Coder	System	21 Jan 2021 14:46:31
User entered 'worsening of tachycardia'	Yvonne De Los Reyes	21 Jan 2021 14:46:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 14:48:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 14:48:43
User entered '18 Oct 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:48:43
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 14:46:15
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 14:48:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 14:48:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes	21 Jan 2021 14:48:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 14:46:15
User entered empty.	System	21 Jan 2021 14:46:15
	Yvonne De Los Reyes	21 Jan 2021 14:46:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).		30 Mar 2021 09:41:34
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 20:59:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error		25 Mar 2021 20:59:45
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).		20 Feb 2021 22:14:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 14:48:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 14:48:43
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:48:43
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 14:46:15
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

US3192730

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 04:07:32
User closed query 'Action taken with inv. prod. appears to be dosing discontinued. Please confirm.' (Site from CRA).		26 Apr 2021 04:07:00
User closed 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).		23 Apr 2021 15:00:31
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 with 'patient experienced "worsening tachycardia" after 1st injection and chose not to get the second injection ' (Site from System).		22 Apr 2021 16:44:56
Query 'Action taken with inv. prod. appears to be dosing discontinued. Please confirm.' answered with 'updated' (Site from CRA).		22 Apr 2021 16:43:13
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	22 Apr 2021 16:42:57
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 16:42:57
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error		22 Apr 2021 16:42:57
DataPoint Un-verified.		20 Apr 2021 17:07:24
User opened query 'Action taken with inv. prod. appears to be dosing discontinued. Please confirm.' (Site from CRA).		20 Apr 2021 17:07:19
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'None (NONE)'	(b) (4) Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'I'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:04:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 14:48:43

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Jan 2021 14:46:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).		31 Mar 2021 03:06:07
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	28 Mar 2021 15:36:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Mar 2021 15:36:18
Data point term sent to Coder	System	25 Mar 2021 21:00:29
Query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'update' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 21:00:29
Coding entries removed.		25 Mar 2021 21:00:22
User entered 'JOINT PAIN POST INJECTION "general"' reason for change: Data Entry Error		25 Mar 2021 21:00:22
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).		03 Mar 2021 05:23:28
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site joint pain, LLT: Injection site joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:36:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 23:36:54
Data point term sent to Coder	System	22 Feb 2021 16:49:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'joint pain post injection'	Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '12 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User closed query 'Data is required. Please provide.' (Site from System).		31 Mar 2021 03:06:15
Query 'Data is required. Please provide.' answered with 'time not collected' (Site from System).	Damaris Atondo (b) (4)	30 Mar 2021 18:28:49
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 18:27:27
User signature succeeded.	System	30 Mar 2021 18:27:27
	John McGettigan (b) (4)	28 Mar 2021 18:41:43
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
User entered empty.	System	22 Feb 2021 16:48:43

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '15 Feb 2021'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User closed query 'Data is required. Please provide.' (Site from System).		31 Mar 2021 03:06:17
Query 'Data is required. Please provide.' answered with 'time not collected' (Site from System).	Damaris Atondo (b) (4)	30 Mar 2021 18:28:52
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Mar 2021 18:27:27
User signature succeeded.	System	30 Mar 2021 18:27:27
	John McGettigan (b) (4)	28 Mar 2021 18:41:43
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
User entered empty.	System	22 Feb 2021 16:48:43

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Related (RELATED)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		14 Apr 2021 05:58:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Updated' (Site from DM).	Saysamone Banks (b) (4) (b) (4)	08 Apr 2021 00:38:38
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 12:37:47
User signature succeeded.	John McGettigan (b) (4) (b) (4)	28 Mar 2021 18:41:43
User entered 'I'	Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	22 Feb 2021 16:48:43

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
DataPoint Verified.		20 Apr 2021 16:56:20
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:41:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	22 Feb 2021 16:48:43
	(b) (4)	

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
User entered '0'	System	22 Feb 2021 16:48:43

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31
User entered '0'	System	22 Feb 2021 16:48:43

US3192730

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:28:31

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:54:09
DataPoint Verified.		20 Apr 2021 16:56:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:57:39
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Botox has been added to con med page' (Site from DM).	Saysamone Banks (b) (4) (b) (4)	30 Mar 2021 21:22:54
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:43:30
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:42:54

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 04:40:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 04:40:18
Data point term sent to Coder	System	04 Oct 2020 22:44:06
User entered 'Anastrozole'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'breast cancer recurrence prevention'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'I'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'mg (mg)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'once daily (QD)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'Oral (ORAL)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'un Apr 2009'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered '0'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User closed query 'Per DM CLR: Please verify if end date should be added as MH #1 BREAST CANCER has resolved on UN APR 2009. Update the eCRF as appropriate. Otherwise, provide explanation.' (Site from DM).		01 Feb 2021 17:29:04
Query 'Per DM CLR: Please verify if end date should be added as MH #1 BREAST CANCER has resolved on UN APR 2009. Update the eCRF as appropriate. Otherwise, provide explanation.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 14:51:00
User opened query 'Per DM CLR: Please verify if end date should be added as MH #1 BREAST CANCER has resolved on UN APR 2009. Update the eCRF as appropriate. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 06:55:35
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered empty.	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 23:26:25
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 22:43:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Oct 2020 22:43:41

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.	(b) (4)	20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 00:38:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 00:38:29
Data point term sent to Coder	System	08 Apr 2021 00:37:42
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	08 Apr 2021 00:36:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 20:35:02
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 Feb 2021 20:35:02
Data point term sent to Coder	System	16 Feb 2021 20:34:36
User entered 'tylenol'	maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		14 Apr 2021 06:38:48
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4) Saysamone Banks (b) (4)	08 Apr 2021 00:36:53
User entered 'joint pain post injection' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 12:37:30
User entered 'headache, body aches and muscle aches,'	maggie Tono (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '1000' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:38:04
User entered '500'	(b) (4)	
	maggie Tono (b) (4)	16 Feb 2021 20:33:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:36:47
User entered 'once daily (QD)'	(b) (4)	
	maggie Tono (b) (4)	16 Feb 2021 20:33:53
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:36:47
User entered '10 Feb 2021'	(b) (4)	
	maggie Tono (b) (4)	16 Feb 2021 20:33:53
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '12 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:36:47
User entered '11 Feb 2021'	(b) (4)	
	maggie Tono (b) (4)	16 Feb 2021 20:33:53
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
DataPoint Verified.		20 Apr 2021 16:58:53
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
User entered empty.	System	08 Apr 2021 00:36:47
User entered '1'	System	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
User entered empty.	System	08 Apr 2021 00:36:47
User entered '1'	System	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:20
User entered empty.	System	08 Apr 2021 00:36:47
User entered '804 (804)'	System	16 Feb 2021 20:33:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:35:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 04:35:34
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:46:26
Data point term sent to Coder	System	08 Apr 2021 00:38:44
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	08 Apr 2021 00:37:47
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	08 Apr 2021 00:37:47
User entered 'advil' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	08 Apr 2021 00:37:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:59:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:59:48
Data point term sent to Coder	System	16 Feb 2021 20:35:37
User entered 'ibuprofen'	maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		14 Apr 2021 06:38:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4) Saysamone Banks (b) (4)	08 Apr 2021 00:37:52
User entered 'joint pain post injection' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 12:37:36
User entered 'body aches, and muscle aches'	maggie Tono (b) (4)	16 Feb 2021 20:34:53
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '600' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:37:47
User entered '200'	(b) (4)	
	maggie Tono (b) (4)	16 Feb 2021 20:34:53
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:38:21
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	08 Apr 2021 00:37:47
User entered 'twice daily (BID)'	maggie Tono (b) (4)	16 Feb 2021 20:34:53
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '13 Feb 2021'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '13 Feb 2021'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
DataPoint Verified.		20 Apr 2021 16:58:56
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
User entered empty.	System	08 Apr 2021 00:38:21
User entered '1'	System	08 Apr 2021 00:37:47
User entered '2'	System	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
User entered empty.	System	08 Apr 2021 00:38:21
User entered '1'	System	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:22
User entered empty.	System	08 Apr 2021 00:38:21
User entered '804 (804)'	System	16 Feb 2021 20:34:53

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:38:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:38:25
Data point term sent to Coder Coding entries removed.	System Saysamone Banks (b) (4)	28 Apr 2021 19:07:22 28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:46:26
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 18:48:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 18:48:14
Data point term sent to Coder User entered 'botox'	System maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:47:51 30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'cosmetic injections'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'na'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'Other (OTHER)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'na'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.	(b) (4)	29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
	(b) (4)	
User entered 'once (ONCE)' reason for change: Data Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:58:58
	(b) (4)	
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
	(b) (4)	
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Mar 2021 18:46:59
User entered 'other (OTHER)' reason for change: Data Entry Error	maggie Tono (b) (4)	30 Mar 2021 18:46:59
	(b) (4)	
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Mar 2021 18:46:50
User entered 'once (ONCE)'	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered empty; reason for change Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '4-6 months'	(b) (4)	
	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered 'subdermal' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4)	
	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.	(b) (4)	29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered '01 Feb 2021' reason for change: Data	(b) (4)	
Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
	(b) (4)	
User entered 'un Feb 2021'	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'Yes (Y)'	(b) (4)	
	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		29 Apr 2021 04:21:22
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Un-verified.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
User entered '01 Feb 2021' reason for change: Data	Saysamone Banks (b) (4)	28 Apr 2021 19:06:36
Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered empty.	(b) (4)	
	maggie Tono (b) (4)	30 Mar 2021 18:46:50
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
DataPoint Verified.		20 Apr 2021 16:58:58
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:46:26
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
User entered empty.	System	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
User entered empty.	System	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:25
User entered empty.	System	30 Mar 2021 18:46:50

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Apr 2021 19:38:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Apr 2021 19:38:25
Data point term sent to Coder	System	28 Apr 2021 19:08:23
User entered 'botox'	Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:07:26
	(b) (4)	

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'cosmetic injections'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'NA'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'Other (OTHER)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'NA'	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:07:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'once (ONCE)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 19:07:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'Other (OTHER)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'Subdermal'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered '15 Oct 2020'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered '0'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered '15 Oct 2020'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
DataPoint Verified.		29 Apr 2021 04:21:24
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
User entered 'No (N)'	(b) (4) Saysamone Banks (b) (4) (b) (4)	28 Apr 2021 19:07:26

US3192730

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
User entered empty.	System	28 Apr 2021 19:07:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
User entered empty.	System	28 Apr 2021 19:07:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:04:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:56:32
User entered empty.	System	28 Apr 2021 19:07:26

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:04:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	29 Apr 2021 15:19:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 04:16:37
User closed query 'Please move Botox to Con. Med. page and change response here to 'no'. Thanks' (Site from CRA).		29 Apr 2021 04:16:25
Query 'Please move Botox to Con. Med. page and change response here to 'no'. Thanks' answered with 'Updated' (Site from CRA).	Saysamone Banks (b) (4)	28 Apr 2021 19:09:33
DataPoint Un-verified.	Saysamone Banks (b) (4)	28 Apr 2021 19:09:29
User entered 'No (N)' reason for change: Data Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 19:09:29
User opened query 'Please move Botox to Con. Med. page and change response here to 'no'. Thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:53:45
DataPoint Verified.		28 Apr 2021 18:45:50
DataPoint Un-verified.		26 Apr 2021 22:17:56
Signature has been broken.		26 Apr 2021 22:17:56
User entered 'Yes (Y)' reason for change: Data Entry Error		26 Apr 2021 22:17:56
DataPoint Verified.		20 Apr 2021 16:59:08
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered 'No (N)'	(b) (4) Yvonne De Los Reyes (b) (4)	21 Jan 2021 22:28:26

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:44

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:04
DataPoint Verified.		20 Apr 2021 17:02:57
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User entered '06 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Yvonne De Los Reyes	20 Feb 2021 13:31:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 14:13:55
Query 'Data is required. Please complete.' answered with 'updated ' (Site from System).		
	Yvonne De Los Reyes	21 Jan 2021 22:30:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	21 Jan 2021 22:25:27
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes	21 Jan 2021 22:25:27
	(b) (4)	
User entered '06 Nov 2020'	Yvonne De Los Reyes	15 Jan 2021 22:05:47
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:44

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:04
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:52:52
User closed query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. Please consider reason for discontinuation to be 'adverse event'.' (Site from CRA).		28 Apr 2021 16:32:59
Query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. Please consider reason for discontinuation to be 'adverse event'.' answered with 'Updated' (Site from CRA).	Saysamone Banks (b) (4)	28 Apr 2021 16:12:44
Signature has been broken.	(b) (4)	
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 16:12:38
User opened query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. Please consider reason for discontinuation to be 'adverse event'.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 00:20:45
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User closed query 'Per CDM: Per the statement listed below please consider amending the response to this data point at it appears that the subject withdrew consent due to medical history. Please reconcile or else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 11:48:30
Query 'Per CDM: Per the statement listed below please consider amending the response to this data point at it appears that the subject withdrew consent due to medical history. Please reconcile or else clarify.' answered with 'Medical history is not listed as an option in the drop down menu for this field' (Site from DM).	Saysamone Banks (b) (4)	30 Mar 2021 21:21:34

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:44

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per the statement listed below please consider amending the response to this data point at it appears that the subject withdrew consent due to medical history. Please reconcile or else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:12:02
User entered 'Other (OTHER)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	20 Feb 2021 13:31:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 14:13:57
Query 'Data is required. Please complete.' answered with 'updated ' (Site from System).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 22:30:49
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 22:25:50
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	21 Jan 2021 22:25:50
User entered 'Other (OTHER)'	Yvonne De Los Reyes (b) (4)	15 Jan 2021 22:05:47

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:44

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)	30 Apr 2021 19:02:04
User signature succeeded.	John McGettigan (b) (4)	28 Apr 2021 22:35:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:52:53
User closed query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. If this is the case, please revise this comment. Thanks' (Site from CRA).		28 Apr 2021 16:33:16
Query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. If this is the case, please revise this comment. Thanks' answered with 'Updated' (Site from CRA).	Saysamone Banks (b) (4)	28 Apr 2021 16:12:55
Signature has been broken.	(b) (4)	
	Saysamone Banks (b) (4)	28 Apr 2021 16:12:38
User entered 'PATIENT DECLINED DOSE 2 DUE TO worsening OF TACHYCARDIA.' reason for change: Data Entry Error	Saysamone Banks (b) (4)	28 Apr 2021 16:12:38
User opened query 'Per AE of 'worsening tachycardia' this AE is the reason subject discontinued dosing portion of study. If this is the case, please revise this comment. Thanks' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	27 Apr 2021 00:21:30
User entered 'patient declined Dose 2 due to a med hx of tachycardia.' reason for change: Data Entry Error	John McGettigan (b) (4)	03 Apr 2021 14:33:15
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	(b) (4)	
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	Yvonne De Los Reyes (b) (4)	20 Feb 2021 13:31:47
User entered empty; reason for change Data Entry Error	System	21 Jan 2021 22:25:50
	System	21 Jan 2021 22:25:27
	System	21 Jan 2021 22:25:27
	Yvonne De Los Reyes (b) (4)	21 Jan 2021 22:25:27

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:04:44

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'patient declined Dose 2 due to a med hx Yvonne De Los Reyes of tachycardia.'	(b) (4)	15 Jan 2021 22:05:47