

US3192086 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:02:38

All time stamps listed in this document are displayed in GMT

US3192086

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Participant ID

US3192086

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

US3192086

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3192086

Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	23
Age Units	YEARS
Age (Derived)	23
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

US3192086

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	6 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3192086

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3192086

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Were any significant conditions reported?

Yes ☒

No ☐

US3192086

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Condition	DEVIATED SEPTUM REPAIR
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

US3192086

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3192086

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Condition	BIPOLAR
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3192086

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3192086

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 12:56
Height (xxx.x)	62.5 in
Weight (xxx.x)	110.4 lb
BMI (xxx.x)	19.91219 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192086

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3192086

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Date of assessment (dd MMM yyyy) 06 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

US3192086

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	06 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3192086

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3192086

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101655

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 ☒

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Height	ND - Not Done
Weight	ND - Not Done

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

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)	06 AUG 2020
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 12:56
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

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)	06 AUG 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 14:22
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3192086

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 13:20

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

US3192086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 AUG 2020

Collection time (00:00-23:59)

13:08 (24 HR)

Collection date and time (derived)

06 AUG 2020 13:08

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:14	06 AUG 2020 13:14
Nasopharyngeal Swab 2	No		

US3192086

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 14:02

PC Open Date & Time

06 AUG 2020 13:40

PC Close Date & Time

06 AUG 2020 16:10

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 99.2 °F

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

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

PC Time Stamp	06 AUG 2020 19:55
PC Open Date & Time	06 AUG 2020 17:05
PC Close Date & Time	07 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:27

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:35

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 15:58

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

99.1 °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

10 AUG 2020 15:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

99.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 16:36

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

12 AUG 2020 17:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

06 AUG 2020 14:03

PC Open Date & Time

06 AUG 2020 13:40

PC Close Date & Time

06 AUG 2020 16:10

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 19:56

PC Open Date & Time

06 AUG 2020 17:05

PC Close Date & Time

07 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:28

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

08 AUG 2020 15:35

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

09 AUG 2020 15:57

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

10 AUG 2020 15:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

11 AUG 2020 16:35

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

12 AUG 2020 17:45

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 14:03
PC Open Date & Time	06 AUG 2020 13:40
PC Close Date & Time	06 AUG 2020 16:10

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:08
PC Open Date & Time	06 AUG 2020 17:05
PC Close Date & Time	07 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

		Yes <input type="checkbox"/>
PC Time stamp	07 AUG 2020 12:28	
PC Open Date & Time	07 AUG 2020 12:00	
PC Close Date & Time	08 AUG 2020 11:59	

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:36
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 15:57
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 ☒

PRODUCTION RELEASE (v12.003

54 of 2258

EAB) (1725)

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 15:01
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

56 of 2258

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 16:35
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 17:46
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3192086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:37:10

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:37:10

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

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)	3 SEP 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 13:27
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:45
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3192086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	3 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:15

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

US3192086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 SEP 2020

Collection time (00:00-23:59)

13:44 (24 HR)

Collection date and time (derived)

3 SEP 2020 13:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 01:45:06

Generated On: 11 Aug 2021 22:02:38

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:40	3 SEP 2020 13:40
Nasopharyngeal Swab 2	No		

US3192086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:37

PC Open Date & Time

03 SEP 2020 14:35

PC Close Date & Time

03 SEP 2020 17:05

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 100.0 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 04 SEP 2020 06:51

PC Open Date & Time 03 SEP 2020 18:00

PC Close Date & Time 04 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

100.0 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	100.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	05 SEP 2020 12:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:00

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

98.5 °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

07 SEP 2020 12:13

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

99.0 °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 SEP 2020 22:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:46

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

03 SEP 2020 14:35

PC Open Date & Time

03 SEP 2020 14:35

PC Close Date & Time

03 SEP 2020 17:05

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:14

PC Open Date & Time

03 SEP 2020 18:00

PC Close Date & Time

04 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

06 SEP 2020 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

07 SEP 2020 12:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

08 SEP 2020 22:33

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

09 SEP 2020 18:46

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 14:35
PC Open Date & Time	03 SEP 2020 14:35
PC Close Date & Time	03 SEP 2020 17:05

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 20:13
PC Open Date & Time	03 SEP 2020 18:00
PC Close Date & Time	04 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:09
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2258

EAB) (1725)

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 ☒

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:47
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3192086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:05

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:56 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:56
Temperature (<i>xxx.x</i>)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 OCT 2020

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

US3192086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 OCT 2020

Collection time (00:00-23:59)

15:21 (24 HR)

Collection date and time (derived)

01 OCT 2020 15:21

US3192086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 01:45:15

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 08:57:27

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 08:22:21

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 08:39:15

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	03 NOV 2020 09:10:20
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 99

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

No ☒

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 NOV 2020 12:00:19

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 09:26:10

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

07 DEC 2020 09:04:45

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 09:04:38

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 12:00:11

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

26 DEC 2020 11:25:42

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" 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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have 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	02 JAN 2021 09:32:57
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 type="radio"/> Yes <input checked="" 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 checked="" 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have 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	09 JAN 2021 00:14:27
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

16 JAN 2021 07:27:10

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

23 JAN 2021 07:36:27

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 FEB 2021 19:50:50

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 11:17:56
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 11:03:59
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 FEB 2021 16:32:19

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 FEB 2021 14:35:48

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 09:13:20

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:20:43

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 08:03:42

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 09:51:32

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 07:35:59

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 07:46:33

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:05:03

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 14:50:31

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 09:42:06

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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="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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 <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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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°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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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02 MAR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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16 MAR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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23 MAR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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30 MAR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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06 APR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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13 APR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 <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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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22 JUN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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06 JUL 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐ 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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 <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"/>

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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 ☐ 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 ☐

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3192086

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:02:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		07 MAR 2021 09:13:13

US3192086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 15:48:15

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 15:48:15

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:43:43

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:43:43

Generated On: 11 Aug 2021 22:02:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 APR 2021
Time of assessment (<i>00:00-23:59</i>)	14:49 (24 HR)
Vital Signs Date and Time (derived)	2 APR 2021 14:49
Temperature (<i>xxx.x</i>)	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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.

US3192086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 APR 2021

Collection time (00:00-23:59)

14:54 (24 HR)

Collection date and time (derived)

2 APR 2021 14:54

US3192086

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 15:30:11

Generated On: 11 Aug 2021 22:02:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192086

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 15:30:11

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192086

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Apr 2021 14:17:26

Generated On: 11 Aug 2021 22:02:38

Date of Contact	2 NOV 2020
Time of Contact	11:35
Date and Time of Contact (derived)	2 NOV 2020 11:35
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" 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 checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	2 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	103.1 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input checked="" type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

320 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	102.0 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	31 OCT 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	1 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	104 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

332 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	3 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 NOV 2020
------	------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	5 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

349 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2258

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Apr 2021 15:30:10

Generated On: 11 Aug 2021 22:02:38

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Apr 2021 17:38:22

Generated On: 11 Aug 2021 22:02:38

Date of Visit	2 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	2 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Apr 2021 14:17:26

Generated On: 11 Aug 2021 22:02:38

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	SICKD1

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 10:42
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	103.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	106 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 NOV 2020

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

US3192086

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

2 NOV 2020

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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 SICKD28

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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) _____

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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.

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3192086

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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

Visit date (dd MMM yyyy)	25 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	UNBLND_DECIDE
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US3192086

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

Form: Unblinding

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Date of updated informed consent (dd MMM yyyy) 25 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 25 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3192086

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

25 FEB 2021 08:55

US3192086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00 - 23:59)

08:57

Collection Date and Time (derived)

25 FEB 2021 08:57

US3192086

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 07 Apr 2021 14:17:26

Generated On: 11 Aug 2021 22:02:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

AEID	
Adverse event	ANEMIA
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	2 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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 checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

AEID	
Adverse event	COVID-LIKE ILLNESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2258

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

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	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)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

AEID	
Adverse event	ADHD (WORSENING)
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)	9 APR 2021
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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2258

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 15:30:07

Generated On: 11 Aug 2021 22:02:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	_____

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

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

Yes ☒

No ☐

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

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

378 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication LAMICTAL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR/ MOOD STABILIZER

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

382 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
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"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER/HEADACHE/PAIN AT
INJECTION SITE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

384 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication FEVER/HEADACHE/PAIN AT
INJECTION SITE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

386 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	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)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication IRON

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication IRON

Prophylaxis Yes ☐
No ☒

Indication SUPPLEMENT

Dose per administration 28

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

390 of 2258

EAB) (1725)

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	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)	04 FEB 2021	
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"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

392 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	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)	30 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

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

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ADHD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2258

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 15:30:09

Generated On: 11 Aug 2021 22:02:38

	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)	9 APR 2021	
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"/>

US3192086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 14:43:41

Generated On: 11 Aug 2021 22:02:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3192086

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:02:38

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3192086

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:02:38

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

US3192086 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

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Form: Participant Creation

Generated On: 11 Aug 2021 22:02:38

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'US3192086'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:35:12

US3192086

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:15

US3192086

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:35:12

US3192086

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Clinic (Clinic)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:15

US3192086

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'SCRN'	System	11 Aug 2020 20:24:15

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered (b) (6) 1996'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:35:13

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '23'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'YEARS'	System	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '23'	System	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Female (F)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'I'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:02:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:42

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '6 Aug 2020'	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Aug 2020'	System	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '2020'	System	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Amendment 1 (1)'	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Zoe Sesma (b) (4)	06 Aug 2020 20:27:34

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 19:35:12

US3192086

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:02:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'I'	System	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:02:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:24:55

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Nasal therapeutic procedures, PT: Nasal septal operation, LLT: Deviated septum repair - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:27:11
Data point term sent to Coder	System	11 Aug 2020 20:26:13
User entered 'Deviated Septum Repair'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'UN UNK 1998'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'UN UNK 1998'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Jan 1998'	System	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '1998'	System	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Jan 1998'	System	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '1998'	System	11 Aug 2020 20:25:30

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:29:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:29:43
Data point term sent to Coder	System	11 Sep 2020 19:28:59
Coding entries removed.	Norma Barrientos (b) (4)	11 Sep 2020 19:28:47
User entered 'Attention Deficit Disorder' reason for change: Data Entry Error	Norma Barrientos (b) (4)	11 Sep 2020 19:28:47
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADD - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:27:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:27:11
Data point term sent to Coder	System	11 Aug 2020 20:26:13
User entered 'ADD'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'UN UNK 2019'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Jan 2019'	System	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '2019'	System	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:25:57

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:58:10
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	Tianna Young (b) (4) (b) (4)	09 Sep 2020 22:21:11
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 05:55:59
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 20:28:12
Data point term sent to Coder	System	11 Aug 2020 20:27:15
User entered 'Bipolar'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'UN UNK 2016'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Jan 2016'	System	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '2016'	System	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:26:24

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:28:12
Data point term sent to Coder	System	11 Aug 2020 20:27:15
User entered 'Depression'	Amanda Hermosillo	11 Aug 2020 20:26:51
	(b) (4)	

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'UN UNK 2016'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'Jan 2016'	System	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '2016'	System	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:26:51

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '12:56'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered '06 Aug 2020 12:56'	System	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '62.5' in	(b) (4)	
	Amanda Hermosillo	11 Aug 2020 20:27:53
DataPoint set to visible.	(b) (4)	
	System	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '110.4' lb	(b) (4)	
	Amanda Hermosillo	11 Aug 2020 20:27:53
DataPoint set to visible.	(b) (4)	
	System	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
Amendment Manager: User entered '19.91219'	System	16 Sep 2020 23:46:15
User entered '19.9'	System	11 Aug 2020 20:27:53
DataPoint set to visible.	System	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'kg/m2'	System	11 Aug 2020 20:27:53
DataPoint set to visible.	System	06 Aug 2020 20:27:40

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Sep 2020 11:22:15
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' answered with 'corrected' (Site from DM).	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:22
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 11:06:32
User entered '98.3' F	Amanda Hermosillo (b) (4)	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	(b) (4) Cynthia Montgomery	02 Sep 2020 15:25:22
User entered 'Other (Other)'	(b) (4) Amanda Hermosillo	11 Aug 2020 20:27:53
	(b) (4)	

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	(b) (4) Cynthia Montgomery	02 Sep 2020 15:25:22
User entered 'Temporal'	(b) (4) Amanda Hermosillo	11 Aug 2020 20:27:53
	(b) (4)	

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:22
User entered '103'	Cynthia Montgomery Amanda Hermosillo (b) (4)	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'bpm'	System	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:22
User entered '14'	Amanda Hermosillo	11 Aug 2020 20:27:53
	(b) (4)	

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'breaths/min'	System	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:22
User entered '119'	Cynthia Montgomery (b) (4)	11 Aug 2020 20:27:53
	Amanda Hermosillo (b) (4)	

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'mmHg'	System	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:22
User entered '85'	Amanda Hermosillo	11 Aug 2020 20:27:53
	(b) (4)	

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered 'mmHg'	System	11 Aug 2020 20:27:53

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48

US3192086

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48

US3192086

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:09

US3192086

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 16:16:52
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 21:43:15
User entered '06 Aug 2020'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:09

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:02:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:28:39

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Urine (URINE)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Negative (NEGATIVE)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tianna Young (b) (4)	09 Sep 2020 22:21:36
User entered '13:00'	(b) (4)	
	Amanda Hermosillo	11 Aug 2020 20:29:12
	(b) (4)	

US3192086

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User entered empty.	System	11 Aug 2020 20:29:12

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'I'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '0'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:02:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:23:48
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	(b) (4) Amanda Hermosillo (b) (4)	11 Aug 2020 20:29:49

US3192086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:06

US3192086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:06

US3192086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Clinic (Clinic)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:06

US3192086

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'VISIT1'	System	11 Aug 2020 20:30:06

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:19:31

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:40:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:40:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 20:19:31
User entered '101655' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:19:31

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 20:19:31

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:15

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:15

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:15

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:15

US3192086

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:02:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:15

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 04:58:38
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:51
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:18:45
User entered '62.5' in	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:51
User entered '110.4' lb	Cynthia Montgomery (b) (4)	11 Aug 2020 20:32:54
	Amanda Hermosillo (b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 04:58:38
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:51
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:18:45
User entered '62.5' in	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:51
User entered '110.4' lb	Cynthia Montgomery (b) (4)	11 Aug 2020 20:32:54
	Amanda Hermosillo (b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Pre-Dose (PREDOSE)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '12:56'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '06 Aug 2020 12:56'	System	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '98.3' F	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Other (Other)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Temporal'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '103'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'bpm'	System	11 Aug 2020 20:32:54

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '14'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'breaths/min'	System	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '119'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '85'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 04:58:38
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'corrected' (Site from DM).	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	02 Sep 2020 15:25:51
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:18:45
User entered '62.5' in	Amanda Hermosillo (b) (4)	11 Aug 2020 20:32:54

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:02:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:25:51
User entered '110.4' lb	Cynthia Montgomery (b) (4)	11 Aug 2020 20:32:54
	Amanda Hermosillo (b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Post-Dose (POSTDOSE)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '14:22'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '06 Aug 2020 14:22'	System	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '98.2' F	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Other (Other)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Temporal'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '78'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'bpm'	System	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '16'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'breaths/min'	System	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '111'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '84'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	11 Aug 2020 20:33:48

US3192086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:28

US3192086

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo	11 Aug 2020 20:30:28

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' answered with 'Form updated.' (Site from DM).	Ipsita Abalokita (b) (4)	11 Sep 2020 18:55:46
	(b) (4)	
Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' answered with 'Form updated.' (Site from DM).	Tianna Young (b) (4)	09 Sep 2020 22:23:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tianna Young (b) (4)	09 Sep 2020 22:23:49
	(b) (4)	
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:24:55
User entered 'Yes (Y)'	Amanda Hermosillo	11 Aug 2020 20:30:43
	(b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	Tianna Young (b) (4)	09 Sep 2020 22:23:49
User entered '06 Aug 2020'	Amanda Hermosillo	11 Aug 2020 20:30:43

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tianna Young (b) (4)	09 Sep 2020 22:23:49
	(b) (4)	
User entered 'Urine (URINE)'	Amanda Hermosillo	11 Aug 2020 20:30:43
	(b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tianna Young (b) (4)	09 Sep 2020 22:23:49
	(b) (4)	
User entered 'Negative (NEGATIVE)'	Amanda Hermosillo	11 Aug 2020 20:30:43
	(b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Per CDM: Please consider marking this data field as "No" since Screening and VID1 occurred on the same day.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:28:29
Query 'Per CDM: Please consider marking this data field as "No" since Screening and VID1 occurred on the same day.' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4)	11 Sep 2020 19:25:55
User entered 'No (N)' reason for change: Data Entry Error	Norma Barrientos (b) (4)	11 Sep 2020 19:25:41
User opened query 'Per CDM: Please consider marking this data field as "No" since Screening and VID1 occurred on the same day.' (Site from DM).	Ipsita Abalokita (b) (4)	11 Sep 2020 19:03:45
Query 'Per CDM: Please complete this section of the form. A required response (Yes or No) is needed for this data field.' canceled (Site from DM).	Ipsita Abalokita (b) (4)	11 Sep 2020 19:02:59
User opened query 'Per CDM: Please complete this section of the form. A required response (Yes or No) is needed for this data field.' (Site from DM).	Ipsita Abalokita (b) (4)	11 Sep 2020 18:55:56
User entered empty; reason for change Data Entry Error	Tianna Young (b) (4)	09 Sep 2020 22:23:49
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:43

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:43

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty; reason for change Data Entry Error	Tianna Young (b) (4)	09 Sep 2020 22:23:49
User entered '13:00'	Amanda Hermosillo	11 Aug 2020 20:30:43

US3192086

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered empty.	System	11 Aug 2020 20:30:43

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '6 Aug 2020'	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '13:20'	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '6 Aug 2020 13:20'	System	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'ONCE'	System	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 20:28:15

US3192086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:59

US3192086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo	11 Aug 2020 20:30:59
	(b) (4)	

US3192086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '13:08'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:30:59

US3192086

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '06 Aug 2020 13:08'	System	11 Aug 2020 20:30:59

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '06 Aug 2020'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '13:14'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '06 Aug 2020 13:14'	System	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered empty.	System	11 Aug 2020 20:31:15

US3192086

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	11 Aug 2020 20:31:19

US3192086

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'I'	System	11 Aug 2020 20:31:19

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:02:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3391b49c-eb1c-4102-8cf8-ccb23ad3cebd' User entered 'Yes (Y)'	System	06 Aug 2020 21:02:41
	System	06 Aug 2020 21:02:41

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:02:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3391b49c-eb1c-4102-8cf8-ccb23ad3cebd' User entered '98.3'	System	06 Aug 2020 21:02:41
	System	06 Aug 2020 21:02:41

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:02:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3391b49c-eb1c-4102-8cf8-ccb23ad3cebd'	System	06 Aug 2020 21:02:41
User entered 'No (N)'	System	06 Aug 2020 21:02:41

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:02:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3391b49c-eb1c-4102-8cf8-ccb23ad3cebd' User entered '06 Aug 2020 14:02'	System	06 Aug 2020 21:02:41
	System	06 Aug 2020 21:02:41

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:55:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '68cc1820-52e0-43aa-90db-b34b24c98d74' User entered 'Yes (Y)'	System	07 Aug 2020 02:55:52
	System	07 Aug 2020 02:55:52

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:55:45', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '68cc1820-52e0-43aa-90db-b34b24c98d74' User entered '99.2'	System	07 Aug 2020 02:55:52
	System	07 Aug 2020 02:55:52

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:55:48', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '68cc1820-52e0-43aa-90db-b34b24c98d74'	System	07 Aug 2020 02:55:52
User entered 'No (N)'	System	07 Aug 2020 02:55:52

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:55:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '68cc1820-52e0-43aa-90db-b34b24c98d74'	System	07 Aug 2020 02:55:52
User entered '06 Aug 2020 19:55'	System	07 Aug 2020 02:55:52

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 2'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:27:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2b03154d-4ff7-418b-ba6e-15c105f2941f' User entered 'Yes (Y)'	System	07 Aug 2020 19:27:56
	System	07 Aug 2020 19:27:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:27:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2b03154d-4ff7-418b-ba6e-15c105f2941f' User entered '99.2'	System	07 Aug 2020 19:27:56
	System	07 Aug 2020 19:27:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:27:48', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2b03154d-4ff7-418b-ba6e-15c105f2941f' User entered 'No (N)'	System	07 Aug 2020 19:27:56
	System	07 Aug 2020 19:27:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:27:51', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2b03154d-4ff7-418b-ba6e-15c105f2941f' User entered '07 Aug 2020 12:27'	System	07 Aug 2020 19:27:56
	System	07 Aug 2020 19:27:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 3'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '26378dae-c502-4fd7-8e6b-2924727e27d0' User entered 'Yes (Y)'	System	08 Aug 2020 22:35:42
	System	08 Aug 2020 22:35:42

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '26378dae-c502-4fd7-8e6b-2924727e27d0' User entered '98.4'	System	08 Aug 2020 22:35:42
	System	08 Aug 2020 22:35:42

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '26378dae-c502-4fd7-8e6b-2924727e27d0'	System	08 Aug 2020 22:35:42
User entered 'No (N)'	System	08 Aug 2020 22:35:42

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:39', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '26378dae-c502-4fd7-8e6b-2924727e27d0'	System	08 Aug 2020 22:35:42
User entered '08 Aug 2020 15:35'	System	08 Aug 2020 22:35:42

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 4'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:47', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '419e9f63-a12f-405a-b1a5-4c3ea253ba73'	System	09 Aug 2020 22:58:08
User entered 'Yes (Y)'	System	09 Aug 2020 22:58:08

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:58:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '419e9f63-a12f-405a-b1a5-4c3ea253ba73'	System	09 Aug 2020 22:58:08
User entered '98.2'	System	09 Aug 2020 22:58:08

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:58:03', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '419e9f63-a12f-405a-b1a5-4c3ea253ba73'	System	09 Aug 2020 22:58:08
User entered 'No (N)'	System	09 Aug 2020 22:58:08

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:58:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '419e9f63-a12f-405a-b1a5-4c3ea253ba73'	System	09 Aug 2020 22:58:08
User entered '09 Aug 2020 15:58'	System	09 Aug 2020 22:58:08

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 5'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f1a8ba2c-3c4b-4b4a-aea0-5a684dfe634d' User entered 'Yes (Y)'	System	10 Aug 2020 22:01:56
	System	10 Aug 2020 22:01:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:48', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f1a8ba2c-3c4b-4b4a-aea0-5a684dfe634d' User entered '99.1'	System	10 Aug 2020 22:01:56
	System	10 Aug 2020 22:01:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f1a8ba2c-3c4b-4b4a-aea0-5a684dfe634d'	System	10 Aug 2020 22:01:56
User entered 'No (N)'	System	10 Aug 2020 22:01:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f1a8ba2c-3c4b-4b4a-aea0-5a684dfe634d' User entered '10 Aug 2020 15:01'	System	10 Aug 2020 22:01:56
	System	10 Aug 2020 22:01:56

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 6'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:49', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c9b00b3b-5920-4868-8227-94e8b735124c' User entered 'Yes (Y)'	System	11 Aug 2020 23:36:16
	System	11 Aug 2020 23:36:16

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:36:11', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c9b00b3b-5920-4868-8227-94e8b735124c' User entered '99.6'	System	11 Aug 2020 23:36:16
	System	11 Aug 2020 23:36:16

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:36:13', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c9b00b3b-5920-4868-8227-94e8b735124c'	System	11 Aug 2020 23:36:16
User entered 'No (N)'	System	11 Aug 2020 23:36:16

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:36:14', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c9b00b3b-5920-4868-8227-94e8b735124c'	System	11 Aug 2020 23:36:16
User entered '11 Aug 2020 16:36'	System	11 Aug 2020 23:36:16

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 7'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '66dd17ed-c3b1-4f26-8637-3142088d2ec9' User entered 'Yes (Y)'	System	13 Aug 2020 00:45:46
	System	13 Aug 2020 00:45:46

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '66dd17ed-c3b1-4f26-8637-3142088d2ec9' User entered '97.5'	System	13 Aug 2020 00:45:46
	System	13 Aug 2020 00:45:46

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '66dd17ed-c3b1-4f26-8637-3142088d2ec9' User entered 'No (N)'	System	13 Aug 2020 00:45:46
	System	13 Aug 2020 00:45:46

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '66dd17ed-c3b1-4f26-8637-3142088d2ec9' User entered '12 Aug 2020 17:45'	System	13 Aug 2020 00:45:46
	System	13 Aug 2020 00:45:46

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-08-06T14:02:51', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e9cfe1d3-0206-4ca4-a69c-b6ef094b9b9b'	System	06 Aug 2020 21:03:17
User entered 'None (1)'	System	06 Aug 2020 21:03:17

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e9cfe1d3-0206-4ca4-a69c-b6ef094b9b9b'	System	06 Aug 2020 21:03:17
User entered 'No (N)'	System	06 Aug 2020 21:03:17

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:05', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e9cfe1d3-0206-4ca4-a69c-b6ef094b9b9b' User entered 'No (N)'	System	06 Aug 2020 21:03:17
	System	06 Aug 2020 21:03:17

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e9cfe1d3-0206-4ca4-a69c-b6ef094b9b9b'	System	06 Aug 2020 21:03:17
User entered 'None (1)'	System	06 Aug 2020 21:03:17

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e9cfe1d3-0206-4ca4-a69c-b6ef094b9b9b' User entered '06 Aug 2020 14:03'	System	06 Aug 2020 21:03:17
	System	06 Aug 2020 21:03:17

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:56:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '48cfa5c0-7f06-45a3-a665-5b3534657c27'	System	07 Aug 2020 02:56:42
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 02:56:42

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:56:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '48cfa5c0-7f06-45a3-a665-5b3534657c27'	System	07 Aug 2020 02:56:42
User entered 'No (N)'	System	07 Aug 2020 02:56:42

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:56:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '48cfa5c0-7f06-45a3-a665-5b3534657c27'	System	07 Aug 2020 02:56:42
User entered 'No (N)'	System	07 Aug 2020 02:56:42

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:56:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '48cfa5c0-7f06-45a3-a665-5b3534657c27'	System	07 Aug 2020 02:56:42
User entered 'None (1)'	System	07 Aug 2020 02:56:42

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T19:56:39', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '48cfa5c0-7f06-45a3-a665-5b3534657c27'	System	07 Aug 2020 02:56:42
User entered '06 Aug 2020 19:56'	System	07 Aug 2020 02:56:42

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 2'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'afff4272-9b5a-4503-89d6-7cae8be32254'	System	07 Aug 2020 19:28:22
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 19:28:22

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'afff4272-9b5a-4503-89d6-7cae8be32254'	System	07 Aug 2020 19:28:22
User entered 'No (N)'	System	07 Aug 2020 19:28:22

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'afff4272-9b5a-4503-89d6-7cae8be32254'	System	07 Aug 2020 19:28:22
User entered 'No (N)'	System	07 Aug 2020 19:28:22

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:17', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'afff4272-9b5a-4503-89d6-7cae8be32254'	System	07 Aug 2020 19:28:22
User entered 'None (1)'	System	07 Aug 2020 19:28:22

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'afff4272-9b5a-4503-89d6-7cae8be32254'	System	07 Aug 2020 19:28:22
User entered '07 Aug 2020 12:28'	System	07 Aug 2020 19:28:22

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 3'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5233702f-22ae-4e0b-b4fd-383f608d92ad'	System	08 Aug 2020 22:36:01
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 22:36:01

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5233702f-22ae-4e0b-b4fd-383f608d92ad' User entered 'No (N)'	System	08 Aug 2020 22:36:01
	System	08 Aug 2020 22:36:01

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5233702f-22ae-4e0b-b4fd-383f608d92ad' User entered 'No (N)'	System	08 Aug 2020 22:36:01
	System	08 Aug 2020 22:36:01

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5233702f-22ae-4e0b-b4fd-383f608d92ad' User entered 'None (1)'	System	08 Aug 2020 22:36:01
	System	08 Aug 2020 22:36:01

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:35:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5233702f-22ae-4e0b-b4fd-383f608d92ad' User entered '08 Aug 2020 15:35'	System	08 Aug 2020 22:36:01
	System	08 Aug 2020 22:36:01

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 4'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:20', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '624d9f66-3150-4e48-8390-0b09d4b8034a'	System	09 Aug 2020 22:57:28
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 22:57:28

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:22', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '624d9f66-3150-4e48-8390-0b09d4b8034a' User entered 'No (N)'	System	09 Aug 2020 22:57:28
	System	09 Aug 2020 22:57:28

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '624d9f66-3150-4e48-8390-0b09d4b8034a' User entered 'No (N)'	System	09 Aug 2020 22:57:28
	System	09 Aug 2020 22:57:28

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '624d9f66-3150-4e48-8390-0b09d4b8034a' User entered 'None (1)'	System	09 Aug 2020 22:57:28
	System	09 Aug 2020 22:57:28

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '624d9f66-3150-4e48-8390-0b09d4b8034a' User entered '09 Aug 2020 15:57'	System	09 Aug 2020 22:57:28
	System	09 Aug 2020 22:57:28

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 5'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '16b96932-1ea0-4a72-a441-0ced7d92ac77'	System	10 Aug 2020 22:01:15
User entered 'None (1)'	System	10 Aug 2020 22:01:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '16b96932-1ea0-4a72-a441-0ced7d92ac77'	System	10 Aug 2020 22:01:15
User entered 'No (N)'	System	10 Aug 2020 22:01:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '16b96932-1ea0-4a72-a441-0ced7d92ac77'	System	10 Aug 2020 22:01:15
User entered 'No (N)'	System	10 Aug 2020 22:01:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '16b96932-1ea0-4a72-a441-0ced7d92ac77'	System	10 Aug 2020 22:01:15
User entered 'None (1)'	System	10 Aug 2020 22:01:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '16b96932-1ea0-4a72-a441-0ced7d92ac77'	System	10 Aug 2020 22:01:15
User entered '10 Aug 2020 15:01'	System	10 Aug 2020 22:01:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 6'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'aa868908-6709-4a96-a80f-42f862bf8d0d'	System	11 Aug 2020 23:35:48
User entered 'None (1)'	System	11 Aug 2020 23:35:48

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'aa868908-6709-4a96-a80f-42f862bf8d0d'	System	11 Aug 2020 23:35:48
User entered 'No (N)'	System	11 Aug 2020 23:35:48

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'aa868908-6709-4a96-a80f-42f862bf8d0d'	System	11 Aug 2020 23:35:48
User entered 'No (N)'	System	11 Aug 2020 23:35:48

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'aa868908-6709-4a96-a80f-42f862bf8d0d'	System	11 Aug 2020 23:35:48
User entered 'None (1)'	System	11 Aug 2020 23:35:48

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:44', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'aa868908-6709-4a96-a80f-42f862bf8d0d'	System	11 Aug 2020 23:35:48
User entered '11 Aug 2020 16:35'	System	11 Aug 2020 23:35:48

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 7'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:51', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2867835-f6e0-4177-8960-d97f037b65f3'	System	13 Aug 2020 00:46:02
User entered 'None (1)'	System	13 Aug 2020 00:46:02

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2867835-f6e0-4177-8960-d97f037b65f3'	System	13 Aug 2020 00:46:02
User entered 'No (N)'	System	13 Aug 2020 00:46:02

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2867835-f6e0-4177-8960-d97f037b65f3' User entered 'No (N)'	System	13 Aug 2020 00:46:02
	System	13 Aug 2020 00:46:02

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2867835-f6e0-4177-8960-d97f037b65f3'	System	13 Aug 2020 00:46:02
User entered 'None (1)'	System	13 Aug 2020 00:46:02

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:45:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2867835-f6e0-4177-8960-d97f037b65f3'	System	13 Aug 2020 00:46:02
User entered '12 Aug 2020 17:45'	System	13 Aug 2020 00:46:02

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'None (0)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered 'No (N)'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T14:03:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f8fc8519-d6d1-433f-b58b-bff6008afa5c' User entered '06 Aug 2020 14:03'	System	06 Aug 2020 21:03:42
	System	06 Aug 2020 21:03:42

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:41', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:43', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:45', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:48', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'None (0)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered 'No (N)'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-06T20:08:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6650ac65-e2e6-4243-b59b-96f094f906bd' User entered '06 Aug 2020 20:08'	System	07 Aug 2020 03:08:57
	System	07 Aug 2020 03:08:57

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 2'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:29', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'None (0)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered 'No (N)'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-07T12:28:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3ab66886-3a04-419c-b57d-2185339dc5b2'	System	07 Aug 2020 19:28:40
User entered '07 Aug 2020 12:28'	System	07 Aug 2020 19:28:40

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 3'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'No interference with activity (1)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'None (0)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'None (0)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'None (0)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'None (0)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'None (0)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:14', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered 'No (N)'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-08T15:36:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '598bf9a5-0f6c-4263-a87e-ca4703e0267f' User entered '08 Aug 2020 15:36'	System	08 Aug 2020 22:36:18
	System	08 Aug 2020 22:36:18

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 4'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:36', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered 'None (0)'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9'	System	09 Aug 2020 22:57:41
User entered 'No (N)'	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-09T15:57:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c84a0526-2ac5-4f3e-8713-8a504986c3a9' User entered '09 Aug 2020 15:57'	System	09 Aug 2020 22:57:41
	System	09 Aug 2020 22:57:41

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 5'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:56', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'None (0)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:00:59', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered 'No (N)'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-10T15:01:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e163d740-f6e2-42b7-acbf-28b8e45ca817' User entered '10 Aug 2020 15:01'	System	10 Aug 2020 22:01:04
	System	10 Aug 2020 22:01:04

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 6'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:21', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:22', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:26', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:28', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77' User entered 'None (0)'	System	11 Aug 2020 23:35:34
	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:29', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77'	System	11 Aug 2020 23:35:34
User entered 'No (N)'	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-11T16:35:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fd4ba9c9-155f-437c-a566-019dabb09e77'	System	11 Aug 2020 23:35:34
User entered '11 Aug 2020 16:35'	System	11 Aug 2020 23:35:34

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 7'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:02', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:03', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:05', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'None (0)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered 'No (N)'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-08-12T17:46:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2e907572-29db-4747-872e-ee9276a51f7d' User entered '12 Aug 2020 17:46'	System	13 Aug 2020 00:46:11
	System	13 Aug 2020 00:46:11

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 20:28:15

US3192086

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:19

US3192086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '13 Aug 2020'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:19

US3192086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:19

US3192086

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	03 Sep 2020 21:24:19

US3192086

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:23

US3192086

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'I'	System	03 Sep 2020 21:24:23

US3192086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:37:10
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:41

US3192086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:37:10
User entered '20 Aug 2020'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:41

US3192086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:37:10
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:41

US3192086

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:37:10
User entered empty.	Zoe Sesma (b) (4)	03 Sep 2020 21:24:41

US3192086

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:37:10
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:44

US3192086

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User entered 'I'	System	03 Sep 2020 21:24:44

US3192086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:53

US3192086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '27 Aug 2020'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:53

US3192086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:53

US3192086

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Zoe Sesma (b) (4)	03 Sep 2020 21:24:53

US3192086

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:24:57

US3192086

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User entered 'I'	System	03 Sep 2020 21:24:57

US3192086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:43:15

US3192086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:43:15

US3192086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Clinic (Clinic)'	Tianna Young (b) (4)	09 Sep 2020 21:43:15

US3192086

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'VISIT2'	System	09 Sep 2020 21:43:15

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '13:27'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '3 Sep 2020 13:27'	System	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '97.2' F	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Oral (Oral)'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '79'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'bpm'	System	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '12'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'breaths/min'	System	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '121'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '87'	Tianna Young (b) (4)	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	09 Sep 2020 21:57:44

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Post-Dose (POSTDOSE)'	Tianna Young (b) (4) (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '14:45'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '3 Sep 2020 14:45'	System	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '97.0' F	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Oral (Oral)'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '68'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'bpm'	System	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '12'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'breaths/min'	System	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '124'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '83'	Tianna Young (b) (4)	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	09 Sep 2020 21:46:11

US3192086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:43:29

US3192086

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:43:29

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Urine (URINE)'	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Negative (NEGATIVE)'	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered empty.	System	09 Sep 2020 21:43:54

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '14:15'	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '3 Sep 2020 14:15'	System	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'ONCE'	System	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:02:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 21:25:12

US3192086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:44:08

US3192086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:44:08

US3192086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '13:44'	Tianna Young (b) (4)	09 Sep 2020 21:44:08

US3192086

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '3 Sep 2020 13:44'	System	09 Sep 2020 21:44:08

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '3 Sep 2020'	Tianna Young (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '13:40'	Tianna Young (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '3 Sep 2020 13:40'	System	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered empty.	System	09 Sep 2020 21:44:32

US3192086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 21:44:38

US3192086

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'I'	System	09 Sep 2020 21:44:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:36:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0aae9555-8819-4e4c-9e70-387bacb3730d' User entered 'Yes (Y)'	System	03 Sep 2020 21:37:03
	System	03 Sep 2020 21:37:03

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:36:56', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0aae9555-8819-4e4c-9e70-387bacb3730d' User entered '97.4'	System	03 Sep 2020 21:37:03
	System	03 Sep 2020 21:37:03

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:36:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0aae9555-8819-4e4c-9e70-387bacb3730d' User entered 'No (N)'	System	03 Sep 2020 21:37:03
	System	03 Sep 2020 21:37:03

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:37:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0aae9555-8819-4e4c-9e70-387bacb3730d' User entered '03 Sep 2020 14:37'	System	03 Sep 2020 21:37:03
	System	03 Sep 2020 21:37:03

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a' User entered 'Yes (Y)'	System	04 Sep 2020 13:51:28
	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:11', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a' User entered '100.0'	System	04 Sep 2020 13:51:28
	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:14', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a'	System	04 Sep 2020 13:51:28
User entered 'Yes (Y)'	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).		16 Sep 2020 13:48:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:54:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Sep 2020 13:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a'	System	04 Sep 2020 13:51:28
User entered '1'	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).		16 Sep 2020 13:48:12
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Yvonne De Los Reyes	13 Sep 2020 16:54:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a'	(b) (4)	
User entered '1'	System	04 Sep 2020 13:51:28
	System	04 Sep 2020 13:51:28
	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T06:51:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9e4cccb7-2869-49fc-b049-3d2bea3e6e1a' User entered '04 Sep 2020 06:51'	System	04 Sep 2020 13:51:28
	System	04 Sep 2020 13:51:28

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 2'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:28', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7' User entered 'Yes (Y)'	System	04 Sep 2020 19:20:43
	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7' User entered '100.0'	System	04 Sep 2020 19:20:43
	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7'	System	04 Sep 2020 19:20:43
User entered 'Yes (Y)'	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).		16 Sep 2020 13:48:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:54:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Sep 2020 19:20:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:39', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7'	System	04 Sep 2020 19:20:43
User entered '1'	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:39', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7' User entered '0'	System	04 Sep 2020 19:20:43
	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd4bae0be-209e-4e8b-97bf-6d1db3bccab7' User entered '04 Sep 2020 12:20'	System	04 Sep 2020 19:20:43
	System	04 Sep 2020 19:20:43

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 3'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60' User entered 'Yes (Y)'	System	05 Sep 2020 19:01:38
	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:28', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60' User entered '100.4'	System	05 Sep 2020 19:01:38
	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60'	System	05 Sep 2020 19:01:38
User entered 'Yes (Y)'	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).		16 Sep 2020 13:48:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:54:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	05 Sep 2020 19:01:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60'	System	05 Sep 2020 19:01:38
User entered '1'	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med page updated ' (Site from System).	(b) (4)	16 Sep 2020 13:48:32
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Yvonne De Los Reyes	13 Sep 2020 16:55:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60'	(b) (4)	
User entered '1'	System	05 Sep 2020 19:01:38
	System	05 Sep 2020 19:01:38
	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0361d84a-2523-46fd-b278-ff87a8815f60' User entered '05 Sep 2020 12:01'	System	05 Sep 2020 19:01:38
	System	05 Sep 2020 19:01:38

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 4'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:00:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '36a48649-1e5b-434b-9d78-9502f3de4ba1' User entered 'Yes (Y)'	System	06 Sep 2020 19:00:56
	System	06 Sep 2020 19:00:56

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:00:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '36a48649-1e5b-434b-9d78-9502f3de4ba1' User entered '98.6'	System	06 Sep 2020 19:00:56
	System	06 Sep 2020 19:00:56

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:00:43', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '36a48649-1e5b-434b-9d78-9502f3de4ba1' User entered 'No (N)'	System	06 Sep 2020 19:00:56
	System	06 Sep 2020 19:00:56

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:00:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '36a48649-1e5b-434b-9d78-9502f3de4ba1' User entered '06 Sep 2020 12:00'	System	06 Sep 2020 19:00:56
	System	06 Sep 2020 19:00:56

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 5'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3703c5d6-28b2-413c-b3f8-fe25d80966aa' User entered 'Yes (Y)'	System	07 Sep 2020 19:13:36
	System	07 Sep 2020 19:13:36

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:11:56', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3703c5d6-28b2-413c-b3f8-fe25d80966aa' User entered '98.5'	System	07 Sep 2020 19:13:36
	System	07 Sep 2020 19:13:36

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:13:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3703c5d6-28b2-413c-b3f8-fe25d80966aa'	System	07 Sep 2020 19:13:36
User entered 'No (N)'	System	07 Sep 2020 19:13:36

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:13:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3703c5d6-28b2-413c-b3f8-fe25d80966aa' User entered '07 Sep 2020 12:13'	System	07 Sep 2020 19:13:36
	System	07 Sep 2020 19:13:36

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 6'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:28:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38211dfa-f3f0-4c81-978a-a93988e07e25'	System	09 Sep 2020 05:29:07
User entered 'Yes (Y)'	System	09 Sep 2020 05:29:07

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:28:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38211dfa-f3f0-4c81-978a-a93988e07e25' User entered '99.0'	System	09 Sep 2020 05:29:07
	System	09 Sep 2020 05:29:07

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:29:02', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38211dfa-f3f0-4c81-978a-a93988e07e25'	System	09 Sep 2020 05:29:07
User entered 'No (N)'	System	09 Sep 2020 05:29:07

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:29:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38211dfa-f3f0-4c81-978a-a93988e07e25' User entered '08 Sep 2020 22:29'	System	09 Sep 2020 05:29:07
	System	09 Sep 2020 05:29:07

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 7'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:41', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'a8dce881-e4c2-4fcd-89a5-a35e0a63114c' User entered 'Yes (Y)'	System	10 Sep 2020 01:46:50
	System	10 Sep 2020 01:46:50

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:45', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'a8dce881-e4c2-4fcd-89a5-a35e0a63114c' User entered '97.6'	System	10 Sep 2020 01:46:50
	System	10 Sep 2020 01:46:50

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:47', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'a8dce881-e4c2-4fcd-89a5-a35e0a63114c'	System	10 Sep 2020 01:46:50
User entered 'No (N)'	System	10 Sep 2020 01:46:50

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:49', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'a8dce881-e4c2-4fcd-89a5-a35e0a63114c'	System	10 Sep 2020 01:46:50
User entered '09 Sep 2020 18:46'	System	10 Sep 2020 01:46:50

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:13', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2faecf1e-ddef-457b-abaf-811b023b0872'	System	03 Sep 2020 21:35:25
User entered 'None (1)'	System	03 Sep 2020 21:35:25

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:18', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2faecf1e-ddef-457b-abaf-811b023b0872'	System	03 Sep 2020 21:35:25
User entered 'No (N)'	System	03 Sep 2020 21:35:25

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2faecf1e-ddef-457b-abaf-811b023b0872'	System	03 Sep 2020 21:35:25
User entered 'No (N)'	System	03 Sep 2020 21:35:25

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:21', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2faecf1e-ddef-457b-abaf-811b023b0872'	System	03 Sep 2020 21:35:25
User entered 'None (1)'	System	03 Sep 2020 21:35:25

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '2faecf1e-ddef-457b-abaf-811b023b0872' User entered '03 Sep 2020 14:35'	System	03 Sep 2020 21:35:25
	System	03 Sep 2020 21:35:25

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:45', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '640a9dd2-27b2-4bf4-8c6b-53d5a46a6d6e'	System	04 Sep 2020 03:14:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 03:14:02

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '640a9dd2-27b2-4bf4-8c6b-53d5a46a6d6e' User entered 'No (N)'	System	04 Sep 2020 03:14:02
	System	04 Sep 2020 03:14:02

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '640a9dd2-27b2-4bf4-8c6b-53d5a46a6d6e' User entered 'No (N)'	System	04 Sep 2020 03:14:02
	System	04 Sep 2020 03:14:02

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:59', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '640a9dd2-27b2-4bf4-8c6b-53d5a46a6d6e'	System	04 Sep 2020 03:14:02
User entered 'None (1)'	System	04 Sep 2020 03:14:02

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:14:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '640a9dd2-27b2-4bf4-8c6b-53d5a46a6d6e' User entered '03 Sep 2020 20:14'	System	04 Sep 2020 03:14:02
	System	04 Sep 2020 03:14:02

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 2'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:49', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c28a2ae2-50c6-4a83-a50f-9f2b41e30a6f'	System	04 Sep 2020 19:20:58
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 19:20:58

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:51', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c28a2ae2-50c6-4a83-a50f-9f2b41e30a6f' User entered 'No (N)'	System	04 Sep 2020 19:20:58
	System	04 Sep 2020 19:20:58

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c28a2ae2-50c6-4a83-a50f-9f2b41e30a6f' User entered 'No (N)'	System	04 Sep 2020 19:20:58
	System	04 Sep 2020 19:20:58

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c28a2ae2-50c6-4a83-a50f-9f2b41e30a6f' User entered 'None (1)'	System	04 Sep 2020 19:20:58
	System	04 Sep 2020 19:20:58

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:20:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'c28a2ae2-50c6-4a83-a50f-9f2b41e30a6f' User entered '04 Sep 2020 12:20'	System	04 Sep 2020 19:20:58
	System	04 Sep 2020 19:20:58

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 3'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '29c4287d-7203-471f-b6a3-04ac2a64b0fd'	System	05 Sep 2020 19:01:53
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 19:01:53

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '29c4287d-7203-471f-b6a3-04ac2a64b0fd' User entered 'No (N)'	System	05 Sep 2020 19:01:53
	System	05 Sep 2020 19:01:53

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:43', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '29c4287d-7203-471f-b6a3-04ac2a64b0fd' User entered 'No (N)'	System	05 Sep 2020 19:01:53
	System	05 Sep 2020 19:01:53

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:44', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '29c4287d-7203-471f-b6a3-04ac2a64b0fd' User entered 'None (1)'	System	05 Sep 2020 19:01:53
	System	05 Sep 2020 19:01:53

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '29c4287d-7203-471f-b6a3-04ac2a64b0fd' User entered '05 Sep 2020 12:01'	System	05 Sep 2020 19:01:53
	System	05 Sep 2020 19:01:53

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 4'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '93e21ab0-cd54-405c-b6bd-a6efca8d91f2'	System	06 Sep 2020 19:01:24
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 19:01:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:13', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '93e21ab0-cd54-405c-b6bd-a6efca8d91f2'	System	06 Sep 2020 19:01:24
User entered 'No (N)'	System	06 Sep 2020 19:01:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:13', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '93e21ab0-cd54-405c-b6bd-a6efca8d91f2'	System	06 Sep 2020 19:01:24
User entered 'No (N)'	System	06 Sep 2020 19:01:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '93e21ab0-cd54-405c-b6bd-a6efca8d91f2'	System	06 Sep 2020 19:01:24
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 19:01:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:21', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '93e21ab0-cd54-405c-b6bd-a6efca8d91f2'	System	06 Sep 2020 19:01:24
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 19:01:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 5'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:22', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38b5d8a8-4139-4691-a324-f5b2e49adc20' User entered 'None (1)'	System	07 Sep 2020 19:09:33
	System	07 Sep 2020 19:09:33

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38b5d8a8-4139-4691-a324-f5b2e49adc20' User entered 'No (N)'	System	07 Sep 2020 19:09:33
	System	07 Sep 2020 19:09:33

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:29', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38b5d8a8-4139-4691-a324-f5b2e49adc20' User entered 'No (N)'	System	07 Sep 2020 19:09:33
	System	07 Sep 2020 19:09:33

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38b5d8a8-4139-4691-a324-f5b2e49adc20' User entered 'None (1)'	System	07 Sep 2020 19:09:33
	System	07 Sep 2020 19:09:33

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38b5d8a8-4139-4691-a324-f5b2e49adc20' User entered '07 Sep 2020 12:09'	System	07 Sep 2020 19:09:33
	System	07 Sep 2020 19:09:33

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 6'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '89654a14-0910-4a31-88b8-b509866b3650'	System	09 Sep 2020 05:33:24
User entered 'None (1)'	System	09 Sep 2020 05:33:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:17', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '89654a14-0910-4a31-88b8-b509866b3650' User entered 'No (N)'	System	09 Sep 2020 05:33:24
	System	09 Sep 2020 05:33:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:18', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '89654a14-0910-4a31-88b8-b509866b3650' User entered 'No (N)'	System	09 Sep 2020 05:33:24
	System	09 Sep 2020 05:33:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '89654a14-0910-4a31-88b8-b509866b3650'	System	09 Sep 2020 05:33:24
User entered 'None (1)'	System	09 Sep 2020 05:33:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:21', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '89654a14-0910-4a31-88b8-b509866b3650' User entered '08 Sep 2020 22:33'	System	09 Sep 2020 05:33:24
	System	09 Sep 2020 05:33:24

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 7'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:52', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bdeb3f35-7322-4067-8ca1-8cf576cd33d8'	System	10 Sep 2020 01:47:03
User entered 'None (1)'	System	10 Sep 2020 01:47:03

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bdeb3f35-7322-4067-8ca1-8cf576cd33d8'	System	10 Sep 2020 01:47:03
User entered 'No (N)'	System	10 Sep 2020 01:47:03

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bdeb3f35-7322-4067-8ca1-8cf576cd33d8' User entered 'No (N)'	System	10 Sep 2020 01:47:03
	System	10 Sep 2020 01:47:03

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bdeb3f35-7322-4067-8ca1-8cf576cd33d8'	System	10 Sep 2020 01:47:03
User entered 'None (1)'	System	10 Sep 2020 01:47:03

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:46:59', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bdeb3f35-7322-4067-8ca1-8cf576cd33d8' User entered '09 Sep 2020 18:46'	System	10 Sep 2020 01:47:03
	System	10 Sep 2020 01:47:03

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2'	System	03 Sep 2020 21:35:46
User entered 'No interference with activity (1)'	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:33', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'None (0)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'None (0)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:36', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'None (0)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'None (0)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'None (0)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered 'No (N)'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T14:35:43', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3b9330f0-630f-476b-98e9-4af7fa866ed2' User entered '03 Sep 2020 14:35'	System	03 Sep 2020 21:35:46
	System	03 Sep 2020 21:35:46

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 14:35'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 17:05'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:26', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:28', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'None (0)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:29', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered 'No (N)'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-03T20:13:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '557b774d-693b-4911-9ba8-69558aa859e9' User entered '03 Sep 2020 20:13'	System	04 Sep 2020 03:13:35
	System	04 Sep 2020 03:13:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 2'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1'	System	04 Sep 2020 19:21:43
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:08', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1'	System	04 Sep 2020 19:21:43
User entered 'Some interference with activity (2)'	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:11', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1'	System	04 Sep 2020 19:21:43
User entered 'Some interference with activity (2)'	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:14', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1' User entered 'None (0)'	System	04 Sep 2020 19:21:43
	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-09-04T12:21:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1'	System	04 Sep 2020 19:21:43
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:37', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1'	System	04 Sep 2020 19:21:43
User entered 'No interference with activity (1)'	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1' User entered 'No (N)'	System	04 Sep 2020 19:21:43
	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-04T12:21:41', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4cc1bbf3-0e37-4558-b468-020770bd91e1' User entered '04 Sep 2020 12:21'	System	04 Sep 2020 19:21:43
	System	04 Sep 2020 19:21:43

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 3'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca'	System	05 Sep 2020 19:02:19
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:01:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca'	System	05 Sep 2020 19:02:19
User entered 'Some interference with activity (2)'	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca'	System	05 Sep 2020 19:02:19
User entered 'Some interference with activity (2)'	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:03', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca' User entered 'None (0)'	System	05 Sep 2020 19:02:19
	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca'	System	05 Sep 2020 19:02:19
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca'	System	05 Sep 2020 19:02:19
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca' User entered 'No (N)'	System	05 Sep 2020 19:02:19
	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-05T12:02:18', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e79f47a9-b5fb-4b91-8a88-3d3a9352c5ca' User entered '05 Sep 2020 12:02'	System	05 Sep 2020 19:02:19
	System	05 Sep 2020 19:02:19

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 4'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db'	System	06 Sep 2020 19:02:07
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:30', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered 'No interference with activity (1)'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:32', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered 'Some interference with activity (2)'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered 'None (0)'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:56', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db'	System	06 Sep 2020 19:02:07
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:01:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered 'No interference with activity (1)'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-09-06T12:02:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered 'No (N)'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-06T12:02:02', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '72159146-3a5a-4b77-b45b-681e46a6e4db' User entered '06 Sep 2020 12:02'	System	06 Sep 2020 19:02:07
	System	06 Sep 2020 19:02:07

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 5'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:06', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'None (0)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'None (0)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85'	System	07 Sep 2020 19:09:21
User entered 'No interference with activity (1)'	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:13', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'None (0)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:14', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'None (0)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'None (0)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:18', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered 'No (N)'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-07T12:09:20', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '716726b9-a533-45c2-8f3e-26530bb09c85' User entered '07 Sep 2020 12:09'	System	07 Sep 2020 19:09:21
	System	07 Sep 2020 19:09:21

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 6'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-09-08T22:33:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:26', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:28', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'None (0)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-08T22:33:31', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered 'No (N)'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-09-08T22:33:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '1182a35a-7fca-44cc-bbc9-30519f21419c' User entered '08 Sep 2020 22:33'	System	09 Sep 2020 05:33:35
	System	09 Sep 2020 05:33:35

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	03 Sep 2020 21:25:12
User entered 'Day 7'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:02', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:03', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:04', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:05', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3' User entered 'None (0)'	System	10 Sep 2020 01:47:14
	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

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 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3'	System	10 Sep 2020 01:47:14
User entered 'No (N)'	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-09-09T18:47:11', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '9f4606fb-b92e-42c8-8dec-4e59d75defc3'	System	10 Sep 2020 01:47:14
User entered '09 Sep 2020 18:47'	System	10 Sep 2020 01:47:14

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 21:25:12

US3192086

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:02:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 21:25:12

US3192086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4)	
	System	13 Sep 2020 16:59:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes	13 Sep 2020 16:59:38
	(b) (4)	
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	13 Sep 2020 16:59:33
User entered 'No (N)'	Yvonne De Los Reyes	13 Sep 2020 16:59:33
	(b) (4)	

US3192086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '12 Sep 2020'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:33

US3192086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:33

US3192086

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:33

US3192086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:45

US3192086

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User entered 'I'	System	13 Sep 2020 16:59:45

US3192086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Sep 2020 17:10:44

US3192086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '20 Sep 2020'	Yvonne De Los Reyes (b) (4)	22 Sep 2020 17:10:44

US3192086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	22 Sep 2020 17:10:44

US3192086

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Yvonne De Los Reyes (b) (4)	22 Sep 2020 17:10:44

US3192086

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	22 Sep 2020 17:10:51

US3192086

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User entered 'I'	System	22 Sep 2020 17:10:51

US3192086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	26 Sep 2020 00:15:41

US3192086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered '25 Sep 2020'	Yvonne De Los Reyes (b) (4)	26 Sep 2020 00:15:41

US3192086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	26 Sep 2020 00:15:41

US3192086

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered empty.	Yvonne De Los Reyes (b) (4)	26 Sep 2020 00:15:41

US3192086

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:06
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	26 Sep 2020 00:15:47

US3192086

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:51:22
User entered 'I'	System	26 Sep 2020 00:15:47

US3192086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 02 NOV 2020 as an UNSCHEDULED Visit, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:11:31
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 02 NOV 2020 as an UNSCHEDULED Visit, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' answered with 'DCF submitted to change unscheduled visit to illness visit. Illness visit has been added into EDC' (Site from DM).	Saysamone Banks (b) (4) (b) (4)	02 Dec 2020 22:33:32
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: It appears PPD central lab has a SARS-CoV-2 serum sample dated 02 NOV 2020 as an UNSCHEDULED Visit, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 05:49:57
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 NOV 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' canceled (Site from DM).		12 Nov 2020 05:46:49
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 02 NOV 2020 is reported under illness visit Day 1 in EDC, however the same is reported in the UNSCHEDULED visit in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).		12 Nov 2020 05:46:38
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:56:58

US3192086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '01 Oct 2020'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:56:58

US3192086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Clinic (Clinic)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:56:58

US3192086

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'VISIT3'	System	02 Oct 2020 15:56:58

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '01 Oct 2020'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '14:56'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '01 Oct 2020 14:56'	System	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 02:50:38
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:47
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Oct 2020 15:57:40
User entered '96.6' F	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Oral (Oral)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered empty.	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '72'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'bpm'	System	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '14'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'breaths/min'	System	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '110'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '75'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'mmHg'	System	02 Oct 2020 15:57:40

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18

US3192086

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18

US3192086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:59:01

US3192086

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '01 Oct 2020'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:59:01

US3192086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:59:34

US3192086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '01 Oct 2020'	Amanda Hermosillo	02 Oct 2020 15:59:34
	(b) (4)	

US3192086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered '15:21'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:59:34

US3192086

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered '01 Oct 2020 15:21'	System	02 Oct 2020 15:59:34

US3192086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 01:45:15
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	02 Oct 2020 15:59:39

US3192086

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'I'	System	02 Oct 2020 15:59:39

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 64'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-06T08:44:20', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '91f99029-edd9-4e1e-a168-1d084be795f2'	System	06 Oct 2020 15:57:30
User entered 'No (N)'	System	06 Oct 2020 15:57:30

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-06T08:57:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '91f99029-edd9-4e1e-a168-1d084be795f2'	System	06 Oct 2020 15:57:30
User entered 'No (N)'	System	06 Oct 2020 15:57:30

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-06T08:57:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '91f99029-edd9-4e1e-a168-1d084be795f2' User entered '06 Oct 2020 08:57:27'	System	06 Oct 2020 15:57:30
	System	06 Oct 2020 15:57:30

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 71'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-13T08:22:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f4b5a78d-8fc2-4d5b-935f-eb921ce932d2'	System	13 Oct 2020 15:22:25
User entered 'No (N)'	System	13 Oct 2020 15:22:25

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-13T08:22:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f4b5a78d-8fc2-4d5b-935f-eb921ce932d2'	System	13 Oct 2020 15:22:25
User entered 'No (N)'	System	13 Oct 2020 15:22:25

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-13T08:22:21', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'f4b5a78d-8fc2-4d5b-935f-eb921ce932d2' User entered '13 Oct 2020 08:22:21'	System	13 Oct 2020 15:22:25
	System	13 Oct 2020 15:22:25

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 78'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-20T08:39:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4530efe4-a85a-4270-a39f-383962f74413'	System	20 Oct 2020 15:39:17
User entered 'No (N)'	System	20 Oct 2020 15:39:17

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-20T08:39:12', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4530efe4-a85a-4270-a39f-383962f74413'	System	20 Oct 2020 15:39:17
User entered 'No (N)'	System	20 Oct 2020 15:39:17

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-10-20T08:39:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '4530efe4-a85a-4270-a39f-383962f74413' User entered '20 Oct 2020 08:39:15'	System	20 Oct 2020 15:39:17
	System	20 Oct 2020 15:39:17

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 92'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		29 Dec 2020 16:10:42
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'patient has been contacted' (Site from DM).	Yvonne De Los Reyes (b) (4)	24 Dec 2020 17:14:08
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:26:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-11-03T09:09:58', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7'	System	03 Nov 2020 16:10:34
User entered 'Yes (Y)'	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-03T09:10:01', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7'	System	03 Nov 2020 16:10:34
User entered 'No (N)'	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-03T09:10:05', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7'	System	03 Nov 2020 16:10:34
User entered 'No (N)'	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-03T09:10:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7'	System	03 Nov 2020 16:10:34
User entered 'Yes (Y)'	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-03T09:10:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7'	System	03 Nov 2020 16:10:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-03T09:10:20', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fdf7e549-98a0-484f-b6a8-4973e20ff5e7' User entered '03 Nov 2020 09:10:20'	System	03 Nov 2020 16:10:34
	System	03 Nov 2020 16:10:34

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 99'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-12T12:00:15', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6945afdd-ebfd-49f0-a2fd-df81c4b9786d'	System	12 Nov 2020 19:00:23
User entered 'No (N)'	System	12 Nov 2020 19:00:23

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-12T12:00:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6945afdd-ebfd-49f0-a2fd-df81c4b9786d'	System	12 Nov 2020 19:00:23
User entered 'No (N)'	System	12 Nov 2020 19:00:23

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-11-12T12:00:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6945afdd-ebfd-49f0-a2fd-df81c4b9786d' User entered '12 Nov 2020 12:00:19'	System	12 Nov 2020 19:00:23
	System	12 Nov 2020 19:00:23

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered 'Day 106'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-18T09:26:02', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '087c138a-6e75-4470-99a1-fa0986f50cc0' User entered 'No (N)'	System	18 Nov 2020 16:26:13
	System	18 Nov 2020 16:26:13

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-18T09:26:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '087c138a-6e75-4470-99a1-fa0986f50cc0'	System	18 Nov 2020 16:26:13
User entered 'No (N)'	System	18 Nov 2020 16:26:13

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-11-18T09:26:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '087c138a-6e75-4470-99a1-fa0986f50cc0' User entered '18 Nov 2020 09:26:10'	System	18 Nov 2020 16:26:13
	System	18 Nov 2020 16:26:13

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 20:28:15

US3192086

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:57:13
Data entry locked.	System	06 Aug 2020 20:28:15
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 20:28:15

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-07T09:04:41', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '762cb74a-3567-4c1f-82a4-0cae7cf8a19d' User entered 'No (N)'	System	07 Dec 2020 16:04:49
	System	07 Dec 2020 16:04:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-07T09:04:43', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '762cb74a-3567-4c1f-82a4-0cae7cf8a19d'	System	07 Dec 2020 16:04:49
User entered 'No (N)'	System	07 Dec 2020 16:04:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-07T09:04:45', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '762cb74a-3567-4c1f-82a4-0cae7cf8a19d' User entered '07 Dec 2020 09:04:45'	System	07 Dec 2020 16:04:49
	System	07 Dec 2020 16:04:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-12-14T09:04:34', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bb18a1dd-78d8-4167-b08e-b050c4273238'	System	14 Dec 2020 16:04:41
User entered 'No (N)'	System	14 Dec 2020 16:04:41

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-12-14T09:04:35', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bb18a1dd-78d8-4167-b08e-b050c4273238'	System	14 Dec 2020 16:04:41
User entered 'No (N)'	System	14 Dec 2020 16:04:41

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-14T09:04:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'bb18a1dd-78d8-4167-b08e-b050c4273238' User entered '14 Dec 2020 09:04:38'	System	14 Dec 2020 16:04:41
	System	14 Dec 2020 16:04:41

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-12-21T12:00:08', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6231dcc7-9a79-4927-84ca-69d7f3b4917b' User entered 'No (N)'	System	21 Dec 2020 19:00:14
	System	21 Dec 2020 19:00:14

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-21T12:00:09', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6231dcc7-9a79-4927-84ca-69d7f3b4917b' User entered 'No (N)'	System	21 Dec 2020 19:00:14

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-21T12:00:11', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6231dcc7-9a79-4927-84ca-69d7f3b4917b' User entered '21 Dec 2020 12:00:11'	System	21 Dec 2020 19:00:14
	System	21 Dec 2020 19:00:14

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2020-12-26T11:25:38', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5253c1d7-965b-4a43-8805-3116e4bc4263'	System	26 Dec 2020 18:25:44
User entered 'No (N)'	System	26 Dec 2020 18:25:44

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-26T11:25:40', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5253c1d7-965b-4a43-8805-3116e4bc4263'	System	26 Dec 2020 18:25:44
User entered 'No (N)'	System	26 Dec 2020 18:25:44

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2020-12-26T11:25:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5253c1d7-965b-4a43-8805-3116e4bc4263' User entered '26 Dec 2020 11:25:42'	System	26 Dec 2020 18:25:44
	System	26 Dec 2020 18:25:44

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-01-02T09:32:42', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90'	System	02 Jan 2021 16:33:07
User entered 'Yes (Y)'	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-02T09:32:44', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90'	System	02 Jan 2021 16:33:07
User entered 'Yes (Y)'	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Please 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-02T09:32:46', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90'	System	02 Jan 2021 16:33:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-02T09:32:49', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90'	System	02 Jan 2021 16:33:07
User entered 'No (N)'	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-02T09:32:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90'	System	02 Jan 2021 16:33:07
User entered 'No (N)'	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-02T09:32:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '0645f2f3-7cee-4781-8c1d-a7d47600da90' User entered '02 Jan 2021 09:32:57'	System	02 Jan 2021 16:33:07
	System	02 Jan 2021 16:33:07

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251'	System	09 Jan 2021 06:14:37
User entered 'Yes (Y)'	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:18', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251'	System	09 Jan 2021 06:14:37
User entered 'Yes (Y)'	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Please 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:20', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251'	System	09 Jan 2021 06:14:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:23', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251'	System	09 Jan 2021 06:14:37
User entered 'No (N)'	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251'	System	09 Jan 2021 06:14:37
User entered 'No (N)'	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-09T00:14:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '938c3b1b-f90f-40cd-b030-89fa2705e251' User entered '09 Jan 2021 00:14:27'	System	09 Jan 2021 06:14:37
	System	09 Jan 2021 06:14:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-01-16T07:27:05', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '44383dc4-4398-4838-aa7a-92a59150969f' User entered 'No (N)'	System	16 Jan 2021 14:27:17
	System	16 Jan 2021 14:27:17

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-16T07:27:07', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '44383dc4-4398-4838-aa7a-92a59150969f' User entered 'No (N)'	System	16 Jan 2021 14:27:17
	System	16 Jan 2021 14:27:17

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-16T07:27:10', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '44383dc4-4398-4838-aa7a-92a59150969f' User entered '16 Jan 2021 07:27:10'	System	16 Jan 2021 14:27:17
	System	16 Jan 2021 14:27:17

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-23T07:36:24', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fbf54d20-86f9-42ce-8fff-5824322dc1e6'	System	23 Jan 2021 14:36:30
User entered 'No (N)'	System	23 Jan 2021 14:36:30

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-23T07:36:25', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fbf54d20-86f9-42ce-8fff-5824322dc1e6'	System	23 Jan 2021 14:36:30
User entered 'No (N)'	System	23 Jan 2021 14:36:30

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-01-23T07:36:27', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fbf54d20-86f9-42ce-8fff-5824322dc1e6' User entered '23 Jan 2021 07:36:27'	System	23 Jan 2021 14:36:30
	System	23 Jan 2021 14:36:30

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-01T19:50:46', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '70e9d03c-2a85-45d1-ba9d-cd03680ae151'	System	02 Feb 2021 02:50:55
User entered 'No (N)'	System	02 Feb 2021 02:50:55

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-01T19:50:48', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '70e9d03c-2a85-45d1-ba9d-cd03680ae151'	System	02 Feb 2021 02:50:55
User entered 'No (N)'	System	02 Feb 2021 02:50:55

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-01T19:50:50', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '70e9d03c-2a85-45d1-ba9d-cd03680ae151'	System	02 Feb 2021 02:50:55
User entered '01 Feb 2021 19:50:50'	System	02 Feb 2021 02:50:55

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-06T11:17:53', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6b275407-bb98-4254-83ce-4650f43f1075'	System	06 Feb 2021 18:18:00
User entered 'No (N)'	System	06 Feb 2021 18:18:00

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-06T11:17:54', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6b275407-bb98-4254-83ce-4650f43f1075'	System	06 Feb 2021 18:18:00
User entered 'No (N)'	System	06 Feb 2021 18:18:00

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-06T11:17:56', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '6b275407-bb98-4254-83ce-4650f43f1075'	System	06 Feb 2021 18:18:00
User entered '06 Feb 2021 11:17:56'	System	06 Feb 2021 18:18:00

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-02-13T11:03:55', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'cb59a101-97f8-4138-b72e-d480bb0d3664'	System	13 Feb 2021 18:07:48
User entered 'No (N)'	System	13 Feb 2021 18:07:48

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-13T11:03:57', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'cb59a101-97f8-4138-b72e-d480bb0d3664'	System	13 Feb 2021 18:07:48
User entered 'No (N)'	System	13 Feb 2021 18:07:48

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-02-13T11:03:59', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'cb59a101-97f8-4138-b72e-d480bb0d3664'	System	13 Feb 2021 18:07:48
User entered '13 Feb 2021 11:03:59'	System	13 Feb 2021 18:07:48

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-02-20T16:32:16', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'ba513508-4724-4730-843c-5e3e49788bcd' User entered 'No (N)'	System	20 Feb 2021 23:32:21
	System	20 Feb 2021 23:32:21

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-20T16:32:17', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'ba513508-4724-4730-843c-5e3e49788bcd' User entered 'No (N)'	System	20 Feb 2021 23:32:21
	System	20 Feb 2021 23:32:21

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-20T16:32:19', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'ba513508-4724-4730-843c-5e3e49788bcd' User entered '20 Feb 2021 16:32:19'	System	20 Feb 2021 23:32:21
	System	20 Feb 2021 23:32:21

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-02-27T07:35:43-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5f6f4413-ea5b-45fb-b281-b40052136232'	System	27 Feb 2021 14:35:51
User entered 'No (N)'	System	27 Feb 2021 14:35:51

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-02-27T07:35:45-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5f6f4413-ea5b-45fb-b281-b40052136232'	System	27 Feb 2021 14:35:51
User entered 'No (N)'	System	27 Feb 2021 14:35:51

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-02-27T07:35:48-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '5f6f4413-ea5b-45fb-b281-b40052136232' User entered '27 Feb 2021 14:35:48'	System	27 Feb 2021 14:35:51
	System	27 Feb 2021 14:35:51

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-07T09:13:17-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2c447c2-9e25-4887-a954-f49dc28420fc'	System	07 Mar 2021 16:13:24
User entered 'No (N)'	System	07 Mar 2021 16:13:24

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-07T09:13:18-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2c447c2-9e25-4887-a954-f49dc28420fc'	System	07 Mar 2021 16:13:24
User entered 'No (N)'	System	07 Mar 2021 16:13:24

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-07T09:13:20-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'e2c447c2-9e25-4887-a954-f49dc28420fc' User entered '07 Mar 2021 09:13:20'	System	07 Mar 2021 16:13:24
	System	07 Mar 2021 16:13:24

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-13T08:20:40-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'eafa046c-d952-4506-a86c-427b765e69ed'	System	13 Mar 2021 15:20:49
User entered 'No (N)'	System	13 Mar 2021 15:20:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-13T08:20:42-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'eafa046c-d952-4506-a86c-427b765e69ed'	System	13 Mar 2021 15:20:49
User entered 'No (N)'	System	13 Mar 2021 15:20:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-03-13T08:20:43-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'eafa046c-d952-4506-a86c-427b765e69ed' User entered '13 Mar 2021 08:20:43'	System	13 Mar 2021 15:20:49
	System	13 Mar 2021 15:20:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-20T08:03:37-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd7c31b7f-9a08-416c-af8f-e15803c8361b'	System	20 Mar 2021 15:03:47
User entered 'No (N)'	System	20 Mar 2021 15:03:47

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-20T08:03:39-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd7c31b7f-9a08-416c-af8f-e15803c8361b'	System	20 Mar 2021 15:03:47
User entered 'No (N)'	System	20 Mar 2021 15:03:47

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-03-20T08:03:42-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'd7c31b7f-9a08-416c-af8f-e15803c8361b' User entered '20 Mar 2021 08:03:42'	System	20 Mar 2021 15:03:47
	System	20 Mar 2021 15:03:47

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-27T09:51:28-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fcda03e2-33d4-4ac7-a870-708e3e430deb' User entered 'No (N)'	System	27 Mar 2021 16:51:43

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-03-27T09:51:30-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fcda03e2-33d4-4ac7-a870-708e3e430deb'	System	27 Mar 2021 16:51:43
User entered 'No (N)'	System	27 Mar 2021 16:51:43

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-03-27T09:51:32-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: 'fcda03e2-33d4-4ac7-a870-708e3e430deb' User entered '27 Mar 2021 09:51:32'	System	27 Mar 2021 16:51:43
	System	27 Mar 2021 16:51:43

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-03T07:35:53-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38e42df1-af5f-4ed7-b880-f1ab6b42731e' User entered 'No (N)'	System	03 Apr 2021 15:54:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-03T07:35:55-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38e42df1-af5f-4ed7-b880-f1ab6b42731e'	System	03 Apr 2021 15:54:49
User entered 'No (N)'	System	03 Apr 2021 15:54:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-03T07:35:59-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '38e42df1-af5f-4ed7-b880-f1ab6b42731e' User entered '03 Apr 2021 07:35:59'	System	03 Apr 2021 15:54:49
	System	03 Apr 2021 15:54:49

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-10T07:46:27-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '468bcfd2-c563-48e3-8435-6757ddc0f676'	System	10 Apr 2021 14:46:37
User entered 'No (N)'	System	10 Apr 2021 14:46:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-10T07:46:31-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '468bcfd2-c563-48e3-8435-6757ddc0f676'	System	10 Apr 2021 14:46:37
User entered 'No (N)'	System	10 Apr 2021 14:46:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-04-10T07:46:33-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '468bcfd2-c563-48e3-8435-6757ddc0f676' User entered '10 Apr 2021 07:46:33'	System	10 Apr 2021 14:46:37
	System	10 Apr 2021 14:46:37

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-17T00:04:59-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '64ffd033-1d29-43f1-bc7c-6648bba9056d'	System	17 Apr 2021 07:05:06
User entered 'No (N)'	System	17 Apr 2021 07:05:06

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-04-17T00:05:00-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '64ffd033-1d29-43f1-bc7c-6648bba9056d'	System	17 Apr 2021 07:05:06
User entered 'No (N)'	System	17 Apr 2021 07:05:06

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-04-17T00:05:03-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '64ffd033-1d29-43f1-bc7c-6648bba9056d' User entered '17 Apr 2021 00:05:03'	System	17 Apr 2021 07:05:06
	System	17 Apr 2021 07:05:06

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-26T14:50:27-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3c52d717-1b93-4d2e-9066-faf3bb5e1193'	System	26 Apr 2021 21:50:38
User entered 'No (N)'	System	26 Apr 2021 21:50:38

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-04-26T14:50:29-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3c52d717-1b93-4d2e-9066-faf3bb5e1193'	System	26 Apr 2021 21:50:38
User entered 'No (N)'	System	26 Apr 2021 21:50:38

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-04-26T14:50:31-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '3c52d717-1b93-4d2e-9066-faf3bb5e1193' User entered '26 Apr 2021 14:50:31'	System	26 Apr 2021 21:50:38
	System	26 Apr 2021 21:50:38

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-05-01T09:42:02-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '730c8117-828d-4bdf-92ad-f95ee49d8ed1'	System	01 May 2021 16:42:09
User entered 'No (N)'	System	01 May 2021 16:42:09

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Have you been exposed to someone with 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 (023CD879-072B-454B-9DE3-7155E9A5FE9B)', Time: '2021-05-01T09:42:03-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '730c8117-828d-4bdf-92ad-f95ee49d8ed1'	System	01 May 2021 16:42:09
User entered 'No (N)'	System	01 May 2021 16:42:09

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-05-01T09:42:06-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '730c8117-828d-4bdf-92ad-f95ee49d8ed1' User entered '01 May 2021 09:42:06'	System	01 May 2021 16:42:09
	System	01 May 2021 16:42:09

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 15:06:29

US3192086

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:02:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:06:29
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 15:06:29

US3192086

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:02:38

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 04:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-03-07T09:13:11-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '02f0986c-5c32-4e13-82b2-30646efa2542'	System	07 Mar 2021 16:13:18
User entered 'No (N)'	System	07 Mar 2021 16:13:18

US3192086

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:02:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (023CD879-072B-454B-9DE3-7155E9A5FEBB)', Time: '2021-03-07T09:13:13-07:00', User OID: 'PatientReportedOutcome (US3192086)', ODM File OID: '02f0986c-5c32-4e13-82b2-30646efa2542' User entered '07 Mar 2021 09:13:13'	System	07 Mar 2021 16:13:18
	System	07 Mar 2021 16:13:18

US3192086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 15:48:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:26:03

US3192086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 15:48:15
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:26:03

US3192086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 15:48:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:26:03

US3192086

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 15:48:15
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:26:03

US3192086

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 15:48:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 15:26:08

US3192086

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:52:18
User entered 'I'	System	02 Nov 2020 15:26:08

US3192086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:37:16

US3192086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:37:16

US3192086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:37:16

US3192086

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:37:16

US3192086

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:37:20

US3192086

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered '1'	System	03 Dec 2020 21:37:20

US3192086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	11 Jan 2021 15:14:21

US3192086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '4 Jan 2021'	Zoe Sesma (b) (4)	11 Jan 2021 15:14:21

US3192086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	11 Jan 2021 15:14:21

US3192086

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Zoe Sesma (b) (4)	11 Jan 2021 15:14:21

US3192086

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	11 Jan 2021 15:14:41

US3192086

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'I'	System	11 Jan 2021 15:14:41

US3192086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:33:21

US3192086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:33:21

US3192086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:33:21

US3192086

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:33:21

US3192086

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:33:26

US3192086

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered '1'	System	11 Feb 2021 20:33:26

US3192086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:05:35
User entered 'No (N)'	Saysamone Banks (b) (4)	30 Mar 2021 17:10:11
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		05 Apr 2021 12:00:19
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'aware the visit is a few days out of window' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 22:06:02
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Apr 2021 22:05:35
User entered '2 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 22:05:35
User entered empty.	Saysamone Banks (b) (4) (b) (4)	30 Mar 2021 17:10:11

US3192086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 22:05:35
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:11
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'VISIT4'	System	30 Mar 2021 17:10:11

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered '2 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered '14:49' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered '2 Apr 2021 14:49'	System	02 Apr 2021 22:07:07
User entered empty.	System	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered '99.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered '77' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'bpm'	System	02 Apr 2021 22:07:07
User entered empty.	System	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User entered '14' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'breaths/min'	System	02 Apr 2021 22:07:07
User entered empty.	System	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Apr 2021 22:07:21
User entered '113' reason for change: Data Entry Error	System	02 Apr 2021 22:07:21
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Apr 2021 22:07:07
User entered '11' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'mmHg'	System	02 Apr 2021 22:07:07
User entered empty.	System	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	02 Apr 2021 22:07:21
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	02 Apr 2021 22:07:21
User entered '85' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 22:07:21
User opened query 'Data is required. Please provide.' (Site from System).	System	02 Apr 2021 22:07:07
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:10:06
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered 'mmHg'	System	02 Apr 2021 22:07:21
User entered empty.	System	30 Mar 2021 17:10:06

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27

US3192086

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27

US3192086

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	30 Mar 2021 17:09:59
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	30 Mar 2021 17:09:59
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 22:08:11
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	30 Mar 2021 17:09:53

US3192086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '2 Apr 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Apr 2021 22:08:11
User entered empty.	Saysamone Banks (b) (4) (b) (4)	30 Mar 2021 17:09:53

US3192086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '14:54' reason for change: Data Entry Error	(b) (4)	02 Apr 2021 22:08:11
User entered empty.	Saysamone Banks (b) (4)	30 Mar 2021 17:09:53
	(b) (4)	

US3192086

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered '2 Apr 2021 14:54'	System	02 Apr 2021 22:08:11
User entered empty.	System	30 Mar 2021 17:09:53

US3192086

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4)	30 Mar 2021 17:09:47

US3192086

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:10:27
User entered '1'	System	30 Mar 2021 17:09:47

US3192086

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:26:03

US3192086

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:26:03

US3192086

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:26:03

US3192086

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:02:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:26:03

US3192086

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:26:07

US3192086

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:02:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 18:26:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '2 Nov 2020'	Tianna Young (b) (4)	06 Apr 2021 23:21:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '11:35'	Tianna Young (b) (4)	06 Apr 2021 23:21:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered '2 Nov 2020 11:35'	System	06 Apr 2021 23:21:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Tianna Young (b) (4)	06 Apr 2021 23:21:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:02:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Yes (Y)'	Tianna Young (b) (4)	06 Apr 2021 23:21:07

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
Signature has been broken.	(b) (4)	
	Tianna Young (b) (4)	14 Apr 2021 15:19:36
User entered 'Day 4 (Day 4)' reason for change:	(b) (4)	
Data Entry Error	Tianna Young (b) (4)	14 Apr 2021 15:19:36
User signature succeeded.	(b) (4)	
	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Day 1 (Day 1)'	(b) (4)	
	Tianna Young (b) (4)	06 Apr 2021 23:23:14
	(b) (4)	

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '2 Nov 2020'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '98'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered '%'	System	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '103.1' F	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Severe (Severe)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Moderate (Moderate)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Severe (Severe)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Severe (Severe)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Moderate (Moderate)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Moderate (Moderate)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'None (None)'	Tianna Young (b) (4)	06 Apr 2021 23:23:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 1 (Day 1)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '30 Oct 2020'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered missing code ND - Not Done.	(b) (4) Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered '%'	System	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '102.0' F	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 00:51:43

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 2 (Day 2)'	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '31 Oct 2020'	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:11:39

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 3 (Day 3)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '1 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered missing code ND - Not Done.	(b) (4) Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered '%'	System	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '104' F	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Mild (Mild)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (None)'	Tianna Young (b) (4)	14 Apr 2021 15:19:27

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 5 (Day 5)'	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '3 Nov 2020'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:23:54

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 6 (Day 6)'	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '4 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:16

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 7 (Day 7)'	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '5 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:42

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 8 (Day 8)'	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '6 Nov 2020'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4) Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:39:53

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Day 9 (Day 9)'	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '7 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'I'	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered empty.	System	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:02:38

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 15:40:14

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered '2 Nov 2020'	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered 'Yes (Y)'	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered 'No (N)'	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02-NOV-2020 is recorded under Covid-19 Assessment in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab / Preclarus Report (Accession No: 1F600311922). Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User signature succeeded.	(b) (4)	15 Apr 2021 05:33:14
	John McGettigan (b) (4)	07 Apr 2021 17:38:22
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02-NOV-2020 is recorded under Covid-19 Assessment in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab / Preclarus Report (Accession No: 1F600311922). Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'DCF has been submitted to PPD today to reflect the change of an illness day 1 visit instead of an unscheduled. ' (Site from DM). User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02-NOV-2020 is recorded under Covid-19 Assessment in EDC, however the data is reported under UNSCHEDULED visit in PPD Central lab / Preclarus Report (Accession No: 1F600311922). Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User entered '2 Nov 2020'	Tianna Young (b) (4)	07 Apr 2021 15:45:13
	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 12:01:09
	Tianna Young (b) (4)	06 Apr 2021 23:21:28
	(b) (4)	

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered empty.	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered 'No (N)'	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered empty.	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 17:38:22
User entered empty.	Tianna Young (b) (4)	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:02:38

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User entered '0'	System	06 Apr 2021 23:21:28

US3192086

Folder: Covid-19 Assessment 02 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:02:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:12:08
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	Tianna Young (b) (4)	06 Apr 2021 23:21:14

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	Tianna Young (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:02:38

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Tianna Young (b) (4) (b) (4)	31 Mar 2021 17:48:34

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:02:38

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	31 Mar 2021 17:48:34
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	02 Dec 2020 22:34:51
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 02NOV2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 09:07:49
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 02NOV2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'a DCF will be submitted, unscheduled visit kit was used for samples collected on 02Nov2020' (Site from DM).	Yvonne De Los Reyes (b) (4)	21 Jan 2021 18:43:19
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 02NOV2020 is reported under Unscheduled visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 05:21:49
User entered '2 Nov 2020'	Saysamone Banks (b) (4)	02 Dec 2020 22:34:51
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:29
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4)	02 Dec 2020 22:34:51
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:29
User entered 'SICKD1'	System	02 Dec 2020 22:34:51

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '2 Nov 2020'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '10:42'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User entered '2 Nov 2020 10:42'	System	02 Dec 2020 22:35:43

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered missing code ND - Not Done.	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
DataPoint set to visible.	(b) (4) System	02 Dec 2020 22:34:51

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered missing code ND - Not Done.	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
DataPoint set to visible.	(b) (4) System	02 Dec 2020 22:34:51

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '103.1' F	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Oral (Oral)'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '106'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Dec 2020 22:35:43

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '14'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Dec 2020 22:35:43

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '122'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Dec 2020 22:35:43

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '71'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:43
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Dec 2020 22:35:43

US3192086

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:54
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '2 Nov 2020'	Saysamone Banks (b) (4)	02 Dec 2020 22:35:54
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:02:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:02
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	02 Dec 2020 22:36:04
	(b) (4)	

US3192086

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:02
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '2 Nov 2020'	Saysamone Banks (b) (4)	02 Dec 2020 22:36:04
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Dec 2020 22:36:42
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:42
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[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 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:42
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	02 Dec 2020 22:36:42

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:36:48

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:36:48

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:36:48

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:36:48

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:36:48
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:02:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 22:36:48

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Dec 2020 22:36:56
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:02:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:36:56
	(b) (4)	

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:02:38

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Saysamone Banks (b) (4)	02 Dec 2020 22:37:03

US3192086

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:02:38

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Saysamone Banks (b) (4)	02 Dec 2020 22:37:03
	(b) (4)	

US3192086

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

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:34

US3192086

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

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:34

US3192086

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

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:34

US3192086

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

Form: Visit Date

Generated On: 11 Aug 2021 22:02:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 16:14:34

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:45:58

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
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 11:45:58

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User entered empty.	System	25 Feb 2021 16:14:53

US3192086

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

Form: Unblinding

Generated On: 11 Aug 2021 22:02:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User entered empty.	System	25 Feb 2021 16:14:53

US3192086

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:14

US3192086

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:14

US3192086

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '08:55' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:36
User entered '8:55'		25 Feb 2021 16:15:14

US3192086

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User entered '25 Feb 2021 08:55'	System	25 Feb 2021 16:15:36
User entered '25 Feb 2021 8:55'	System	25 Feb 2021 16:15:14

US3192086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:02:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:28

US3192086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:02:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:28

US3192086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:02:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '08:57'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:15:28

US3192086

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:49:18
User entered '25 Feb 2021 08:57'	System	25 Feb 2021 16:15:28

US3192086

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:02:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:19:33
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 23:56:02
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Apr 2021 23:56:02
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 16:06:01
User entered 'No (N)'	(b) (4) Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:52

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 00:12:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 00:12:43
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 00:12:03
User entered 'Anemia'	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per page 50 of CCGs version 5.0, "Not Applicable" is to be recorded ONLY when "clinical event is prior to IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 12:36:38
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
Query 'Per CDM: Per page 50 of CCGs version 5.0, "Not Applicable" is to be recorded ONLY when "clinical event is prior to IP". Please review and update accordingly. Thank you. ' answered with 'updated' (Site from DM).	maggie Tono (b) (4)	12 Apr 2021 21:01:29
Signature has been broken.	maggie Tono (b) (4)	12 Apr 2021 21:01:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4)	12 Apr 2021 21:01:10
User opened query 'Per CDM: Per page 50 of CCGs version 5.0, "Not Applicable" is to be recorded ONLY when "clinical event is prior to IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:21:05
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 14:17:26
User entered 'Not Applicable (NOT APPLICABLE)'		06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 00:11:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 00:11:47
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Apr 2021 00:11:47
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 00:11:03
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	06 Apr 2021 00:11:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Apr 2021 00:11:03
User entered '0'	(b) (4), (b) (6) (b) (4) (b) (4)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '1' reason for change: Data Entry Error	(b) (4) (d) (4), (b) (6)	06 Apr 2021 00:11:47
User entered '0'		06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 00:11:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 00:11:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	06 Apr 2021 00:11:47
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 00:11:03
User entered empty.	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:02:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 00:11:03

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 04:41:47
Query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' answered with 'due to ecrf guidelines this is the correct term to use as a protocol' (Site from DM).	maggie Tono (b) (4) (b) (4)	28 Apr 2021 21:06:08
User opened query 'Per MM, please confirm if a more specific diagnosis was identified. If yes, please update event term ' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 21:49:56
User signature succeeded.	John McGettigan (b) (4) (b) (4)	15 Apr 2021 15:30:11
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:17:49
Data point term sent to Coder	System	14 Apr 2021 18:16:51
User entered 'covid-like illness'	Tianna Young (b) (4) (b) (4)	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'Yes (Y)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '30 Oct 2020'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '7 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Not Related (NOT RELATED)'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '1'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 18:16:48
	(b) (4)	

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:02:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 18:16:48

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 08:53:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 08:53:48
Data point term sent to Coder	System	14 Apr 2021 18:36:17
User entered 'ADHD (worsening)'	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:36:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:36:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 18:36:37
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:36:09
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:37:15
User entered '1'		14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '1' reason for change: Data Entry Error	(b) (4) (d) (4), (b) (6)	14 Apr 2021 18:37:15
User entered '0'		14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:36:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Apr 2021 18:36:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	14 Apr 2021 18:36:37
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Apr 2021 18:36:09
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:36:09

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 18:36:37

US3192086

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:02:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 18:36:09

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:19:33
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User closed query 'Per DM CLR-Requery: Response noted, however, please confirm what has been updated as there is no conmed recorded for the note PAIN AT INJECTION SITE and HEADACHE on Day 1-4 Dose 2 in the ConMed eCRF page. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:59:43
Query 'Per DM CLR-Requery: Response noted, however, please confirm what has been updated as there is no conmed recorded for the note PAIN AT INJECTION SITE and HEADACHE on Day 1-4 Dose 2 in the ConMed eCRF page. Please reconcile and update as appropriate, otherwise clarify.' answered with 'reconciled ' (Site from DM).	Yvonne De Los Reyes (b) (4)	23 Jan 2021 23:32:08
User opened query 'Per DM CLR-Requery: Response noted, however, please confirm what has been updated as there is no conmed recorded for the note PAIN AT INJECTION SITE and HEADACHE on Day 1-4 Dose 2 in the ConMed eCRF page. Please reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:43:45
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1-4, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).		29 Oct 2020 16:26:54

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1-4, Painmaggie Tono at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'this has been updated ' (Site from DM). User opened query 'Per DM CLR: Per Diary Dose 2 Day 1-4, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). User entered 'Yes (Y)'	(b) (4) (b) (4) (b) (4), (b) (6) (b) (4)	21 Oct 2020 22:32:15 21 Oct 2020 06:32:30 09 Sep 2020 22:03:51

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:08:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:08:45
Data point term sent to Coder	System	09 Sep 2020 22:07:32
User entered 'Adderall'	Tianna Young (b) (4)	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Attention deficit hyperactivity disorder'	(b) (4) Tianna Young (b) (4)	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '15'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'mg (mg)'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'once daily (QD)'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'UN UNK 2019'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
Signature has been broken.	(b) (4) (d) (4), (b) (6)	14 Apr 2021 18:28:01
User entered 'No (N)' reason for change: Data Entry Error		14 Apr 2021 18:28:01
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) Tianna Young (b) (4) (b) (4)	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		14 Apr 2021 18:28:01
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	14 Apr 2021 18:27:49
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 18:27:49
User entered '7 Apr 2021' reason for change: Data Entry Error		14 Apr 2021 18:27:49
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 22:06:49
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:06:49

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 07:46:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Sep 2020 07:46:36
Data point term sent to Coder Coding entries removed.	System	09 Sep 2020 22:20:53
	Tianna Young (b) (4)	09 Sep 2020 22:20:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE, PRODUCTSYNONYM: LAMICTAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:17:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:17:42
Data point term sent to Coder User entered 'Lamictal'	System	09 Sep 2020 22:16:45
	Tianna Young (b) (4)	09 Sep 2020 22:15:50

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'bipolar/ MOOD STABILIZER' reason for change: Data Entry Error	(b) (4)	
	Tianna Young (b) (4)	09 Sep 2020 22:20:44
	(b) (4)	
User entered 'Mood stabilizer'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '100'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'mg (mg)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'once daily (QD)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'UN UNK 2016'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 22:15:50
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:15:50

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:15:50

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:15:50

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 01:04:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 01:04:32
Data point term sent to Coder Coding entries removed.	System Crystal Mata (b) (4)	02 Oct 2020 01:03:57 02 Oct 2020 01:03:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:20:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Sep 2020 22:20:46
Data point term sent to Coder User entered 'Escitalopram'	System Tianna Young (b) (4)	09 Sep 2020 22:19:49 09 Sep 2020 22:19:15

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User closed query 'Per DM CLR: Please review indication. Update to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:54:32
Query 'Per DM CLR: Please review indication. Update to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED FIELD TO REFLECT MH=DEPRESSION.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	02 Oct 2020 01:03:40
User entered 'DEPRESSION' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	02 Oct 2020 01:03:21
User opened query 'Per DM CLR: Please review indication. Update to reflect the underlying medical condition that this medication is being used to treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:09:20
User entered 'Antidepressant'	Tianna Young (b) (4) (b) (4)	09 Sep 2020 22:19:15

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '20'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'mg (mg)'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'once daily (QD)'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'UN UNK 2016'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered '0'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'Yes (Y)'	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 22:20:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 22:20:19
User entered 'No (N)' reason for change: Data Entry Error	Tianna Young (b) (4)	09 Sep 2020 22:20:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 22:19:15
User entered empty.	Tianna Young (b) (4)	09 Sep 2020 22:19:15
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:19:15

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 22:19:15

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Sep 2020 22:19:15

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
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)	23 Jan 2021 23:34:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Jan 2021 23:34:11
Data point term sent to Coder	System	23 Jan 2021 23:33:21
Coding entries removed.	Yvonne De Los Reyes	23 Jan 2021 23:33:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 16:59:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Sep 2020 16:59:52
Data point term sent to Coder	System	13 Sep 2020 16:58:47
User entered 'Tylenol'	Yvonne De Los Reyes	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'FEVER/headache/pain at injection site'	(b) (4)	23 Jan 2021 23:33:06
reason for change: Data Entry Error	(b) (4)	
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:20:38
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' answered with 'Does not meet criteria for AE ' (Site from DM).	Norma Barrientos (b) (4)	17 Oct 2020 13:23:28
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 04:58:52
User entered 'Fever'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '325'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:06
Query 'Per DM CLR: Con Med start date this does not match the data recorded on the eDiary. Please review and reconcile dates. Update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:31:22
User opened query 'Per DM CLR: Con Med start date this does not match the data recorded on the eDiary. Please review and reconcile dates. Update as appropriate. ' (Site from DM).		01 Oct 2020 06:29:36
User entered '04 Sep 2020'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '0'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:06
User entered 'Yes (Y)'	Yvonne De Los Reyes	13 Sep 2020 16:58:19
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:06
User entered empty.	Yvonne De Los Reyes	13 Sep 2020 16:58:19
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Yvonne De Los Reyes	23 Jan 2021 23:33:06
User entered 'No (N)'	(b) (4)	
	Yvonne De Los Reyes	13 Sep 2020 16:58:19
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User entered empty.	System	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User entered empty.	System	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:40
User entered empty.	System	13 Sep 2020 16:58:19

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
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)	24 Jan 2021 20:46:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	24 Jan 2021 20:46:50
Data point term sent to Coder	System	23 Jan 2021 23:34:27
Coding entries removed.	Yvonne De Los Reyes	23 Jan 2021 23:33:57
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.	(b) (4)	13 Sep 2020 17:00:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Sep 2020 17:00:52
Data point term sent to Coder	System	13 Sep 2020 16:59:50
User entered 'Ibuprofen'	Yvonne De Los Reyes	13 Sep 2020 16:59:00
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If FEVER/HEADACHE/PAIN AT INJECTION SITE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 07:23:16
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If FEVER/HEADACHE/PAIN AT INJECTION SITE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'patient not an ae criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	17 Feb 2021 22:41:44

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If FEVER/HEADACHE/PAIN AT INJECTION SITE are considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER/HEADACHE/PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:45:39
User entered 'FEVER/headache/pain at injection site' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	23 Jan 2021 23:33:57
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:21:06
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' answered with 'Does not meet reporting criteria for an AE' (Site from DM).	Norma Barrientos (b) (4)	17 Oct 2020 13:24:15
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 04:57:34
User entered 'Fever'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '200'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:57
User entered '04 Sep 2020'	Yvonne De Los Reyes	13 Sep 2020 16:59:00
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '0'	Yvonne De Los Reyes (b) (4)	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:57
User entered 'Yes (Y)'	Yvonne De Los Reyes	13 Sep 2020 16:59:00
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '05 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Jan 2021 23:33:57
User entered empty.	Yvonne De Los Reyes	13 Sep 2020 16:59:00
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Yvonne De Los Reyes	23 Jan 2021 23:33:57
User entered 'No (N)'	(b) (4)	
	Yvonne De Los Reyes	13 Sep 2020 16:59:00
	(b) (4)	

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User entered empty.	System	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User entered empty.	System	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:12:46
User entered empty.	System	13 Sep 2020 16:59:00

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Dec 2020 21:39:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Dec 2020 21:39:55
Data point term sent to Coder	System	03 Dec 2020 21:39:25
User entered 'Iron'	(b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4)	09 Feb 2021 12:52:28
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Yvonne De Los Reyes	01 Feb 2021 14:37:17
' answered with 'updated ' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes	01 Feb 2021 14:37:10
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4)	01 Feb 2021 06:42:51
' (Site from DM).	(b) (4), (b) (6)	
User entered 'No (N)'		03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User closed query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 21:00:06
Query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' answered with 'CORRECT AS IS. PATIENT IS TAKING IRON AS A SUPPLEMENT AND NOT FOR PROPHYLAXIS. THANK YOU.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	11 Dec 2020 02:52:37
User opened query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 02:54:30
User entered 'supplement'		03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '325'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
	(b) (4)	
Signature has been broken.	Tianna Young (b) (4)	14 Apr 2021 15:59:07
	(b) (4)	
User entered '02 Nov 2020' reason for change: Data Entry Error	Tianna Young (b) (4)	14 Apr 2021 15:59:07
	(b) (4)	
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'UN Nov 2020'	(b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Dec 2020 21:39:16

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Apr 2021 00:15:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 00:15:44
Data point term sent to Coder	System	06 Apr 2021 00:15:03
User entered 'iron'	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'supplement'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User entered '28'	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:28:30
User entered '04 Feb 2021' reason for change: Data Entry Error		14 Apr 2021 18:28:30
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'UN Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:17:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 00:14:22

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 16:19:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 16:19:53
Data point term sent to Coder	System	14 Apr 2021 16:19:39
User entered 'ibuprofen'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'covid-like illness'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '600'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'mg (mg)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'three times daily (TID)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '30 Oct 2020'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '31 Oct 2020'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User entered '3'	System	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User entered '1'	System	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:08
User entered '804 (804)'	System	14 Apr 2021 16:19:23

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
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)	14 Apr 2021 16:20:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 16:20:54
Data point term sent to Coder	System	14 Apr 2021 16:20:40
User entered 'tylenol'	Tianna Young (b) (4) (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'covid-like illness'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '500'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'mg (mg)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'as needed (PRN)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '30 Oct 2020'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '1 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User entered empty.	System	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User entered empty.	System	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:10
User entered empty.	System	14 Apr 2021 16:19:56

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
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)	14 Apr 2021 16:20:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 16:20:54
Data point term sent to Coder	System	14 Apr 2021 16:20:40
User entered 'tylenol'	Tianna Young (b) (4) (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'covid-like illness'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '1000'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'mg (mg)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'as needed (PRN)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Oral (ORAL)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '2 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '2 Nov 2020'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	Tianna Young (b) (4)	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User entered empty.	System	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User entered empty.	System	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:13:13
User entered empty.	System	14 Apr 2021 16:20:31

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 18:31:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 18:31:05
Data point term sent to Coder	System	14 Apr 2021 18:30:10
User entered 'Adderall'	(b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'ADHD'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '20'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered '0'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED] [REDACTED]	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	15 Apr 2021 15:30:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:02:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Apr 2021 18:29:43

US3192086

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:02:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 14:43:42
	(b) (4)	
User entered 'No (N)'	Yvonne De Los Reyes	13 Sep 2020 16:55:56
	(b) (4)	