

US3122047 (Prod: M3 Wake Research, Inc - M3 Wake)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:54:34

All time stamps listed in this document are displayed in GMT

US3122047

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

[Participant ID](#)

US3122047

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

US3122047

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 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

US3122047

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 20:31:10

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Date of Informed Consent (*dd MMM yyyy*) 27 JUL 2020

Month and Year of Informed Consent (derived) JUL 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

US3122047

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Condition	ALLERGY TO PENICILLIN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Condition	INGUINAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN AUG 2017
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 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2017
Start Year (derived)	2017
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

US3122047

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN JUL 2017
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 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2017
Start Year (derived)	2017
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

US3122047

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Condition	UNBILICAL HERNIA
Start date (dd MMM yyyy)	(b) (6) 1991
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 AUG 2017
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1991
Start Year (derived)	1991
Stop Month and Year (derived)	AUG 2017
Stop Year (derived)	2017

US3122047

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Condition	SEASONAL ALLERGIES - POLLEN
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	17:41 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:41
Height (<i>xxx.x</i>)	71 in
Weight (<i>xxx.x</i>)	250 lb
BMI (<i>xxx.x</i>)	34.94083 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:31:11

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

LAB STAFF TO PRODUCE
VACCINES

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 20:31:11

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

What was the date of randomization? (dd MMM yyyy) 27 JUL 2020

What was the participant's randomization number? 142093

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

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)	27 JUL 2020
Time of assessment (00:00-23:59)	17:41 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 17:41
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

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)	27 JUL 2020
Time of assessment (00:00-23:59)	19:15 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 19:15
Temperature (xxx.x)	97.5 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	103 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 27 JUL 2020

What was the treatment time? (00:00-23:59) 18:41 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 18:41

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JUL 2020
Collection time (00:00-23:59)	18:20 (24 HR)
Collection date and time (derived)	27 JUL 2020 18:20

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Collection date (dd MMM yyyy)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:26	27 JUL 2020 18:26
Nasopharyngeal Swab 2	No		

US3122047

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 JUL 2020 19:01

PC Close Date & Time

27 JUL 2020 21:31

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 27 JUL 2020 22:26

PC Close Date & Time 28 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

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

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

28 JUL 2020 18:58

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

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

98.0 °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

29 JUL 2020 15:53

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

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

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 19:23

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

31 JUL 2020 21:32

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 21:44

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 18:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 JUL 2020 19:01

PC Close Date & Time

27 JUL 2020 21:31

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 JUL 2020 22:26

PC Close Date & Time

28 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 JUL 2020 18:56

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 19:29

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

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

30 JUL 2020 19:22

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 21:59

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 15:02

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 18:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 19:01

PC Close Date & Time

27 JUL 2020 21:31

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 22:26

PC Close Date & Time

28 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

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 ☒

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

		Yes <input type="checkbox"/>
PC Time stamp	28 JUL 2020 18:54	
PC Open Date & Time	28 JUL 2020 12:00	
PC Close Date & Time	29 JUL 2020 11:59	

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

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 ☒

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EAB) (1725)

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US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

		Yes <input type="checkbox"/>
PC Time stamp	29 JUL 2020 19:29	
PC Open Date & Time	29 JUL 2020 12:00	
PC Close Date & Time	30 JUL 2020 11:59	

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

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 ☒

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EAB) (1725)

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 19:23
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

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 ☒

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 21:59
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

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 ☒

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EAB) (1725)

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 15:01
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 18:03
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3122047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	VISIT2

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	17:10 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 17:10
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to ☒
Adverse Event ☒
Physician withheld dose due to ☐
Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by ☐
Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3122047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 AUG 2020

Collection time (00:00-23:59)

17:54 (24 HR)

Collection date and time (derived)

27 AUG 2020 17:54

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:56	27 AUG 2020 17:56
Nasopharyngeal Swab 2	No		

US3122047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:32:29

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:32:29

Generated On: 11 Aug 2021 21:54:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 OCT 2020
Time of assessment (00:00-23:59)	14:16 (24 HR)
Vital Signs Date and Time (derived)	05 OCT 2020 14:16
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:32:29

Generated On: 11 Aug 2021 21:54:34

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.

US3122047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:32:29

Generated On: 11 Aug 2021 21:54:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 OCT 2020
Collection time (00:00-23:59)	15:42 (24 HR)
Collection date and time (derived)	05 OCT 2020 15:42

US3122047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:11

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	26 SEP 2020 01:08:00
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

03 OCT 2020 01:19:42

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 11:20:17
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 06:56:51

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

31 OCT 2020 00:25:10

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 <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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 NOV 2020 05:47:31
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 06:03:12
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 04:01:45
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

02 DEC 2020 06:14:36

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

09 DEC 2020 04:28:58

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

16 DEC 2020 00:33:57

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:26:53

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 05:28:26
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

13 JAN 2021 16:32:05

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

20 JAN 2021 00:17:37

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 00:45:23

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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	03 FEB 2021 02:32:07
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

10 FEB 2021 00:30:06

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

17 FEB 2021 05:31:51

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

24 FEB 2021 06:09:05

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

03 MAR 2021 01:11:53

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

10 MAR 2021 02:36:15

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 05:18:31
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

24 MAR 2021 05:47:49

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

31 MAR 2021 04:22:23

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

07 APR 2021 00:44:55

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

14 APR 2021 05:32:45

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

21 APR 2021 05:31:57

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 10:32:26

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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="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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 306

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 <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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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23 JAN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

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27 FEB 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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03 APR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

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15 MAY 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

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22 MAY 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

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03 JUL 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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°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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

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14 AUG 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

Date and time of submission	
Patient Cloud Open Date & Time	24 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 ☐

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3122047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:54:34

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		03 MAR 2021 01:12:13

US3122047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:30:56

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 21:30:56

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	VISIT4

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 17:44:16

Generated On: 11 Aug 2021 21:54:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	16:05 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 16:05
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3122047

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

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.

US3122047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3122047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 16:40:09

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 18:57:09

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:10:05

Generated On: 11 Aug 2021 21:54:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3122047

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:10:05

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3122047

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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 _____

US3122047

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

Date of Contact	16 OCT 2020
Time of Contact	13:30
Date and Time of Contact (derived)	16 OCT 2020 13:30
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>

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

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"/>

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

	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	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

286 of 1816

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

	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 checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

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 checked="" type="radio"/>
	Mild	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

Date of Visit	16 OCT 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	16 OCT 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

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 21:30:56

Generated On: 11 Aug 2021 21:54:34

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

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)	

US3122047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	SICKD1

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 13:50
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	97 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

US3122047

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 OCT 2020

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

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) _____

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

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.

US3122047

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 12 Mar 2021 17:20:39

Generated On: 11 Aug 2021 21:54:34

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3122047

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

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

Visit date (dd MMM yyyy)	21 JAN 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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US3122047

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Date of updated informed consent (dd MMM yyyy) 21 JAN 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) 21 JAN 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 _____

US3122047

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	21 JAN 2021 15:20
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US3122047

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

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

Collection date (dd MMM yyyy)	21 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:23
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Collection Date and Time (derived)	21 JAN 2021 15:23
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US3122047

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID

Adverse event

HYPERSENSITIVITY RASH -
BILATERAL ELBOWS
(MACULAR - URTICARIAL)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

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

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID	
Adverse event	DEPRESSION
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)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID

Adverse event

DIARRHEA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID

Adverse event

PHARYNGITIS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

AEID	
Adverse event	BORDERLINE HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 05 Apr 2021 18:55:26

Generated On: 11 Aug 2021 21:54:34

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Mar 2021 15:04:22

Generated On: 11 Aug 2021 21:54:34

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

Yes ☒

No ☐

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

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Name of Medication PEPTO BISMOL

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	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)		15 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)		18 OCT 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"/>

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Name of Medication
GENERIC DAYQUIL
(ACETAMINOPHEN,
PHENYLEPHRINE HCL,
DEXTROMETHORPHAN HBR)

Prophylaxis
Yes ☐
No ☒

Indication
UPPER RESPIRATORY
INFECTION

Dose per administration
30

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

Q4H

Route of administration
Oral ☒
Topical ☐

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EAB) (1725)

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US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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"/>
<hr/>		
If route of administration is Other, specify _____		
<hr/>		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
<hr/>		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
<hr/>		
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"/>

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Name of Medication
GENERIC NYQUIL
(ACETAMINOPHEN,
DOXYLAMINE SUCCINATE,
DEXTROMETHORPHAN HBR)

Prophylaxis
Yes ☐
No ☒

Indication
UPPER RESPIRATORY
INFECTION

Dose per administration
30

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

QD

Route of administration
Oral ☒
Topical ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	19 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)	22 OCT 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"/>

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication POSSIBLE HTN

Dose per administration 12.5

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	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 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"/>

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

Name of Medication ZOLOFT

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 18:46:55

Generated On: 11 Aug 2021 21:54:34

	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)		3 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"/>

US3122047

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 10 Mar 2021 18:32:31

Generated On: 11 Aug 2021 21:54:34

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3122047

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 20:31:10

Generated On: 11 Aug 2021 21:54:34

Date of dosing discontinuation (dd MMM yyyy) 27 AUG 2020

Primary reason for dosing discontinuation

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

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE #1 - PARTICIPANT CHOICE.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:54:34

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

US3122047 (Prod: M3 Wake Research, Inc - M3 Wake)

US3122047

Form: Participant Creation

Generated On: 11 Aug 2021 21:54:34

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'US3122047'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Jul 2020 21:54:08

US3122047

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:13

US3122047

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:06:57
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'Illness visit data added' (Site from DM).	Leah Corts (b) (4)	11 Feb 2021 19:56:33
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 03:34:20
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 21:54:09

US3122047

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:13

US3122047

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'SCRN'	System	28 Jul 2020 21:38:13

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 21:54:10

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '28'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'YEARS'	System	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '28'	System	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:54:34

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:38:40

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Jul 2020'	System	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2020'	System	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:00

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 21:54:09

US3122047

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:54:34

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'I'	System	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:54:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:03:42

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 22:05:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 22:05:11
Data point term sent to Coder	System	30 Jul 2020 22:04:34
User entered 'Allergy to Penicillin'	Aubrey Farray (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'un UNK 2008'	Aubrey Farray (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Jan 2008'	System	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2008'	System	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered empty.	System	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered empty.	System	30 Jul 2020 22:04:11

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per DM CLR: Please specify the location of HERNIA REPAIR (e.g., Hiatal, Right Inguinal, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 11:10:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:48:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 13:48:50
Query 'Per DM CLR: Please specify the location of HERNIA REPAIR (e.g., Hiatal, Right Inguinal, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'Clarified, other hernia details to be entered in Med Hx' (Site from DM).	Leah Corts (b) (4)	03 Sep 2020 13:48:25
Data point term sent to Coder	System	03 Sep 2020 13:47:59
Coding entries removed.	Leah Corts (b) (4)	03 Sep 2020 13:47:55
User entered 'Inguinal HERNIA REPAIR' reason for change: Data Entry Error	Leah Corts (b) (4)	03 Sep 2020 13:47:55
User opened query 'Per DM CLR: Please specify the location of HERNIA REPAIR (e.g., Hiatal, Right Inguinal, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 08:49:01

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 22:07:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Jul 2020 22:07:14
Data point term sent to Coder	System	30 Jul 2020 22:05:35
User entered 'Hernia Repair'	Aubrey Farray (b) (4)	30 Jul 2020 22:05:16
	(b) (4)	

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'un Aug 2017'	Aubrey Farrray (b) (4)	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	Aubrey Farrray (b) (4)	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'un Aug 2017'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Aug 2017'	System	30 Jul 2020 22:05:16

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2017'	System	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Aug 2017'	System	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2017'	System	30 Jul 2020 22:05:16

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 13:50:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 13:50:43
Data point term sent to Coder	System	03 Sep 2020 13:50:04
User entered 'Inguinal Hernia'	Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'UN Jul 2017'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'UN Aug 2017'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Jul 2017'	System	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2017'	System	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Aug 2017'	System	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2017'	System	03 Sep 2020 13:50:01

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 13:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 13:52:44
Data point term sent to Coder	System	03 Sep 2020 13:51:07
User entered 'Unbilical Hernia'	Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '(b) (6) 1991'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'UN Aug 2017'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '(b) (6) 1991'	System	03 Sep 2020 13:50:38

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '1991'	System	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Aug 2017'	System	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '2017'	System	03 Sep 2020 13:50:38

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Pollen allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 12:48:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 12:48:26
Data point term sent to Coder	System	25 Mar 2021 12:47:56
User entered 'Seasonal allergies - pollen'	(b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered 'UN UNK 1998'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'Jan 1998'	System	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '1998'	System	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered empty.	System	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered empty.	System	25 Mar 2021 12:47:05

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17:41'	Aubrey Farrah (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered '27 Jul 2020 17:41'	System	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '71' in	(b) (4)	
	Aubrey Farrray (b) (4)	30 Jul 2020 22:06:59
DataPoint set to visible.	(b) (4)	
	System	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '250' lb	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:06:59
DataPoint set to visible.	(b) (4) System	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
Amendment Manager: User entered '34.94083'	System	16 Sep 2020 23:37:06
User entered '34.9'	System	30 Jul 2020 22:06:59
DataPoint set to visible.	System	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'kg/m2'	System	30 Jul 2020 22:06:59
DataPoint set to visible.	System	28 Jul 2020 21:39:08

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered '97.7' F	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 01:58:15
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' answered with 'updated' (Site from DM).	Brad Killebrew (b) (4)	08 Sep 2020 15:38:49
User entered empty; reason for change Data Entry Error	Brad Killebrew (b) (4)	08 Sep 2020 15:38:43
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" and "If Other, specify" fields accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 10:55:33
User entered 'Other (Other)' reason for change: Data Entry Error	Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered 'Oral (Oral)'	Aubrey Farrray (b) (4) (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered empty.	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered '84'	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'bpm'	System	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered '14'	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'breaths/min'	System	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered '157'	Aubrey Farray (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'mmHg'	System	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:54:41
User entered '88'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User entered 'mmHg'	System	30 Jul 2020 22:06:59

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 21:14:45

US3122047

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45

US3122047

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:07:11

US3122047

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
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)	08 Sep 2020 03:50:15
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 13:11:15
User entered '27 Jul 2020'	Aubrey Farrah (b) (4) (b) (4)	30 Jul 2020 22:07:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Lab Staff to Produce Vaccines'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'I'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:54:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:14:45
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 13:44:11

US3122047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:34

US3122047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:34

US3122047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:34

US3122047

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'VISIT1'	System	28 Jul 2020 21:39:34

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 22:14:10

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:05:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:05:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jul 2020 22:14:10
User entered '142093' (non-conformant).	RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 22:14:10

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 08:12:23
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:12:22
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'unable to change at this point' (Site from System).	Brad Killebrew (b) (4)	01 Oct 2020 15:55:22
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 20:58:03
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Pt is listed at risk due to their profession.' (Site from DM).	Leah Corts (b) (4)	30 Sep 2020 18:43:20
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 16:03:01
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:02:53
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	28 Jul 2020 21:39:57
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT(b) (4)	27 Jul 2020 22:14:10

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:57

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:57

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:57

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:57

US3122047

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:54:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:39:57

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '71' in	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '250' lb	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '71' in	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '250' lb	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Pre-Dose (PREDOSE)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17:41'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Jul 2020 17:41'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '97.7' F	(b) (4) Aubrey Farra (b) (4) (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Oral (Oral)'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '84'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'bpm'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '14'	(b) (4) Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'breaths/min'	System	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	03 Aug 2020 19:17:22
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Data correct; not clinically significant' (Site from System).	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:10:29
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	30 Jul 2020 22:09:10
User entered '157'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '88'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '71' in	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:54:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Leah Corts (b) (4)	17 Aug 2020 20:52:31
User entered '250' lb	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Post-Dose (POSTDOSE)'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) Aubrey Farray (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Aug 2020 19:26:18
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data correct; not clinically significant' (Site from System).	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:10:48
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		30 Jul 2020 22:09:10
User entered '19:15'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Jul 2020 19:15'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '97.5' F reason for change: Data Entry Error	System	30 Jul 2020 22:09:31
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Aubrey Farray (b) (4)	30 Jul 2020 22:09:31
User entered '97.5' (non-conformant).	(b) (4)	
	System	30 Jul 2020 22:09:10
	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	System	30 Jul 2020 22:09:47
User opened query 'Data is required. Please provide.' (Site from System).	Aubrey Farray (b) (4)	30 Jul 2020 22:09:47
User entered empty.	(b) (4)	
	System	30 Jul 2020 22:09:10
	Aubrey Farray (b) (4)	30 Jul 2020 22:09:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '79'	(b) (4) Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'bpm'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '16'	(b) (4) Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'breaths/min'	System	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '153'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:09:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	20 Aug 2020 15:05:36
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'data is correct, Not clinically Significant' (Site from System).	Leah Corts (b) (4)	20 Aug 2020 14:06:14
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Jul 2020 22:09:10
User entered '103'	Aubrey Farray (b) (4) (b) (4)	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	30 Jul 2020 22:09:10

US3122047

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Aubrey Farrey (b) (4)	30 Jul 2020 22:10:56

US3122047

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) Aubrey Farrah (b) (4)	30 Jul 2020 22:10:56

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18:41'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Jul 2020 18:41'	System	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'ONCE'	System	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 21:40:23

US3122047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:47:27

US3122047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:47:27

US3122047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18:20'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:47:27

US3122047

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Jul 2020 18:20'	System	31 Jul 2020 12:47:27

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Jul 2020'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18:26'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Jul 2020 18:26'	System	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	31 Jul 2020 12:48:06

US3122047

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:41:55

US3122047

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	13 Aug 2020 14:41:55

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 19:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 21:31'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 22:26'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 2'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:57:08', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '64027f3b-372b-42c4-885f-751cb094b28a' User entered 'Yes (Y)'	System	28 Jul 2020 22:58:48
	System	28 Jul 2020 22:58:48

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:58:27', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '64027f3b-372b-42c4-885f-751cb094b28a' User entered '97.6'	System	28 Jul 2020 22:58:48
	System	28 Jul 2020 22:58:48

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:58:30', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '64027f3b-372b-42c4-885f-751cb094b28a' User entered 'No (N)'	System	28 Jul 2020 22:58:48
	System	28 Jul 2020 22:58:48

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:58:44', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '64027f3b-372b-42c4-885f-751cb094b28a' User entered '28 Jul 2020 18:58'	System	28 Jul 2020 22:58:48
	System	28 Jul 2020 22:58:48

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 3'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T15:52:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '08f72147-626b-4e14-aceb-f711c5d7ac55'	System	29 Jul 2020 19:53:40
User entered 'Yes (Y)'	System	29 Jul 2020 19:53:40

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T15:53:23', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '08f72147-626b-4e14-aceb-f711c5d7ac55' User entered '98.0'	System	29 Jul 2020 19:53:40
	System	29 Jul 2020 19:53:40

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T15:53:29', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '08f72147-626b-4e14-aceb-f711c5d7ac55'	System	29 Jul 2020 19:53:40
User entered 'No (N)'	System	29 Jul 2020 19:53:40

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T15:53:38', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '08f72147-626b-4e14-aceb-f711c5d7ac55'	System	29 Jul 2020 19:53:40
User entered '29 Jul 2020 15:53'	System	29 Jul 2020 19:53:40

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 4'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:28', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e1621d38-2ccf-4fd2-9b53-352c19f8d706' User entered 'Yes (Y)'	System	30 Jul 2020 23:23:41
	System	30 Jul 2020 23:23:41

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:32', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e1621d38-2ccf-4fd2-9b53-352c19f8d706' User entered '96.2'	System	30 Jul 2020 23:23:41
	System	30 Jul 2020 23:23:41

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:35', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e1621d38-2ccf-4fd2-9b53-352c19f8d706' User entered 'No (N)'	System	30 Jul 2020 23:23:41
	System	30 Jul 2020 23:23:41

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:38', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e1621d38-2ccf-4fd2-9b53-352c19f8d706'	System	30 Jul 2020 23:23:41
User entered '30 Jul 2020 19:23'	System	30 Jul 2020 23:23:41

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 5'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:31:25', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '673bcf1a-5d1f-4a71-a4b1-32e21b6850b8' User entered 'Yes (Y)'	System	01 Aug 2020 01:32:09
	System	01 Aug 2020 01:32:09

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:32:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '673bcf1a-5d1f-4a71-a4b1-32e21b6850b8' User entered '97.5'	System	01 Aug 2020 01:32:09
	System	01 Aug 2020 01:32:09

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:32:04', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '673bcf1a-5d1f-4a71-a4b1-32e21b6850b8' User entered 'No (N)'	System	01 Aug 2020 01:32:09
	System	01 Aug 2020 01:32:09

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:32:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '673bcf1a-5d1f-4a71-a4b1-32e21b6850b8' User entered '31 Jul 2020 21:32'	System	01 Aug 2020 01:32:09
	System	01 Aug 2020 01:32:09

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 6'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T21:43:50', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '370c3de3-7c92-4d66-bdbe-054c7236beff' User entered 'Yes (Y)'	System	02 Aug 2020 01:44:08
	System	02 Aug 2020 01:44:08

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T21:43:55', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '370c3de3-7c92-4d66-bdbe-054c7236beff' User entered '97.9'	System	02 Aug 2020 01:44:08
	System	02 Aug 2020 01:44:08

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T21:44:02', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '370c3de3-7c92-4d66-bdbe-054c7236beff' User entered 'No (N)'	System	02 Aug 2020 01:44:08
	System	02 Aug 2020 01:44:08

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T21:44:06', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '370c3de3-7c92-4d66-bdbe-054c7236beff' User entered '01 Aug 2020 21:44'	System	02 Aug 2020 01:44:08
	System	02 Aug 2020 01:44:08

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 7'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:14:20', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '19ff4c9b-c1c1-4b56-945a-54a9d9addf59'	System	02 Aug 2020 22:14:33
User entered 'Yes (Y)'	System	02 Aug 2020 22:14:33

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:14:24', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '19ff4c9b-c1c1-4b56-945a-54a9d9addf59' User entered '97.9'	System	02 Aug 2020 22:14:33
	System	02 Aug 2020 22:14:33

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:14:28', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '19ff4c9b-c1c1-4b56-945a-54a9d9addf59'	System	02 Aug 2020 22:14:33
User entered 'No (N)'	System	02 Aug 2020 22:14:33

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:14:30', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '19ff4c9b-c1c1-4b56-945a-54a9d9addf59'	System	02 Aug 2020 22:14:33
User entered '02 Aug 2020 18:14'	System	02 Aug 2020 22:14:33

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 19:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 21:31'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 22:26'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 2'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:55:18', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '85f54319-ef21-4c0f-a8d6-434502d5a040'	System	28 Jul 2020 22:56:14
User entered 'Does not interfere with activity (2)'	System	28 Jul 2020 22:56:14

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:55:43', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '85f54319-ef21-4c0f-a8d6-434502d5a040' User entered 'No (N)'	System	28 Jul 2020 22:56:14
	System	28 Jul 2020 22:56:14

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:55:50', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '85f54319-ef21-4c0f-a8d6-434502d5a040' User entered 'No (N)'	System	28 Jul 2020 22:56:14
	System	28 Jul 2020 22:56:14

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:56:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '85f54319-ef21-4c0f-a8d6-434502d5a040'	System	28 Jul 2020 22:56:14
User entered 'None (1)'	System	28 Jul 2020 22:56:14

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:56:13', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '85f54319-ef21-4c0f-a8d6-434502d5a040' User entered '28 Jul 2020 18:56'	System	28 Jul 2020 22:56:14
	System	28 Jul 2020 22:56:14

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 3'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:02', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3c9c1c1f-3c03-4e91-a2cb-7d8a13bc4131'	System	29 Jul 2020 23:29:17
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 23:29:17

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:05', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3c9c1c1f-3c03-4e91-a2cb-7d8a13bc4131' User entered 'No (N)'	System	29 Jul 2020 23:29:17
	System	29 Jul 2020 23:29:17

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:08', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3c9c1c1f-3c03-4e91-a2cb-7d8a13bc4131' User entered 'No (N)'	System	29 Jul 2020 23:29:17
	System	29 Jul 2020 23:29:17

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:10', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3c9c1c1f-3c03-4e91-a2cb-7d8a13bc4131' User entered 'None (1)'	System	29 Jul 2020 23:29:17
	System	29 Jul 2020 23:29:17

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:13', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3c9c1c1f-3c03-4e91-a2cb-7d8a13bc4131' User entered '29 Jul 2020 19:29'	System	29 Jul 2020 23:29:17
	System	29 Jul 2020 23:29:17

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 4'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:44', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd8582834-ba64-4f61-b29b-df370db800cd' User entered 'None (1)'	System	30 Jul 2020 23:22:57
	System	30 Jul 2020 23:22:57

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:47', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd8582834-ba64-4f61-b29b-df370db800cd' User entered 'No (N)'	System	30 Jul 2020 23:22:57
	System	30 Jul 2020 23:22:57

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:49', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd8582834-ba64-4f61-b29b-df370db800cd' User entered 'No (N)'	System	30 Jul 2020 23:22:57
	System	30 Jul 2020 23:22:57

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:50', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd8582834-ba64-4f61-b29b-df370db800cd' User entered 'None (1)'	System	30 Jul 2020 23:22:57
	System	30 Jul 2020 23:22:57

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:53', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd8582834-ba64-4f61-b29b-df370db800cd' User entered '30 Jul 2020 19:22'	System	30 Jul 2020 23:22:57
	System	30 Jul 2020 23:22:57

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 5'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:27', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'fd6ac9b3-7f11-4500-b518-324f3017c5e9'	System	01 Aug 2020 01:59:43
User entered 'None (1)'	System	01 Aug 2020 01:59:43

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:30', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'fd6ac9b3-7f11-4500-b518-324f3017c5e9'	System	01 Aug 2020 01:59:43
User entered 'No (N)'	System	01 Aug 2020 01:59:43

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:33', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'fd6ac9b3-7f11-4500-b518-324f3017c5e9'	System	01 Aug 2020 01:59:43
User entered 'No (N)'	System	01 Aug 2020 01:59:43

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:38', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'fd6ac9b3-7f11-4500-b518-324f3017c5e9' User entered 'None (1)'	System	01 Aug 2020 01:59:43
	System	01 Aug 2020 01:59:43

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:41', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'fd6ac9b3-7f11-4500-b518-324f3017c5e9'	System	01 Aug 2020 01:59:43
User entered '31 Jul 2020 21:59'	System	01 Aug 2020 01:59:43

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 6'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:48', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'ebc2bb4f-69ca-4e11-b3a0-3a8f61b7872e' User entered 'None (1)'	System	01 Aug 2020 19:02:20
	System	01 Aug 2020 19:02:20

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:50', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'ebc2bb4f-69ca-4e11-b3a0-3a8f61b7872e' User entered 'No (N)'	System	01 Aug 2020 19:02:20
	System	01 Aug 2020 19:02:20

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:52', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'ebc2bb4f-69ca-4e11-b3a0-3a8f61b7872e' User entered 'No (N)'	System	01 Aug 2020 19:02:20
	System	01 Aug 2020 19:02:20

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:02:14', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'ebc2bb4f-69ca-4e11-b3a0-3a8f61b7872e' User entered 'None (1)'	System	01 Aug 2020 19:02:20
	System	01 Aug 2020 19:02:20

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:02:17', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'ebc2bb4f-69ca-4e11-b3a0-3a8f61b7872e' User entered '01 Aug 2020 15:02'	System	01 Aug 2020 19:02:20
	System	01 Aug 2020 19:02:20

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 7'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:01:06', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'bdf6e8bd-31d6-4e07-bb62-aa157047ef68'	System	02 Aug 2020 22:01:18
User entered 'None (1)'	System	02 Aug 2020 22:01:18

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:01:09', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'bdf6e8bd-31d6-4e07-bb62-aa157047ef68'	System	02 Aug 2020 22:01:18
User entered 'No (N)'	System	02 Aug 2020 22:01:18

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:01:11', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'bdf6e8bd-31d6-4e07-bb62-aa157047ef68' User entered 'No (N)'	System	02 Aug 2020 22:01:18
	System	02 Aug 2020 22:01:18

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:01:13', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'bdf6e8bd-31d6-4e07-bb62-aa157047ef68'	System	02 Aug 2020 22:01:18
User entered 'None (1)'	System	02 Aug 2020 22:01:18

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:01:15', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'bdf6e8bd-31d6-4e07-bb62-aa157047ef68'	System	02 Aug 2020 22:01:18
User entered '02 Aug 2020 18:01'	System	02 Aug 2020 22:01:18

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 19:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 21:31'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '27 Jul 2020 22:26'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 2'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:53:56', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:17', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:23', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:27', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:29', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:32', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'None (0)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:49', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered 'No (N)'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-28T18:54:57', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'd34d2d3a-2cde-4578-ad17-ca4b9b7333b3' User entered '28 Jul 2020 18:54'	System	28 Jul 2020 22:54:59
	System	28 Jul 2020 22:54:59

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 3'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:18', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:20', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:22', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:24', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:26', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:28', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'None (0)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:34', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered 'No (N)'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-29T19:29:36', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '03463c7e-82a1-4652-a6b1-85645745883d' User entered '29 Jul 2020 19:29'	System	29 Jul 2020 23:29:38
	System	29 Jul 2020 23:29:38

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 4'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:58', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35'	System	30 Jul 2020 23:23:14
User entered 'None (0)'	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:22:59', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35' User entered 'None (0)'	System	30 Jul 2020 23:23:14
	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:01', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35'	System	30 Jul 2020 23:23:14
User entered 'None (0)'	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:02', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35' User entered 'None (0)'	System	30 Jul 2020 23:23:14
	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:04', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35' User entered 'None (0)'	System	30 Jul 2020 23:23:14
	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:05', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35' User entered 'None (0)'	System	30 Jul 2020 23:23:14
	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:08', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35'	System	30 Jul 2020 23:23:14
User entered 'No (N)'	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-30T19:23:10', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b0a07fe4-bdda-4901-98c8-9ef95f5e4b35'	System	30 Jul 2020 23:23:14
User entered '30 Jul 2020 19:23'	System	30 Jul 2020 23:23:14

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 5'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:03', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f'	System	01 Aug 2020 01:59:25
User entered 'No interference with activity (1)'	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f'	System	01 Aug 2020 01:59:25
User entered 'No interference with activity (1)'	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:09', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf4-4351-9591-c8e56eb19b5f' User entered 'None (0)'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:11', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f' User entered 'None (0)'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:13', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f' User entered 'None (0)'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:17', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f' User entered 'None (0)'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:19', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf4351-9591-c8e56eb19b5f' User entered 'No (N)'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-07-31T21:59:22', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6a6d226f-dbf-4351-9591-c8e56eb19b5f' User entered '31 Jul 2020 21:59'	System	01 Aug 2020 01:59:25
	System	01 Aug 2020 01:59:25

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 6'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:16', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:19', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:20', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:22', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:30', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:32', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'None (0)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:34', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered 'No (N)'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-01T15:01:37', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8149c23b-474a-4ce4-9c25-b53004ec4fc1' User entered '01 Aug 2020 15:01'	System	01 Aug 2020 19:01:39
	System	01 Aug 2020 19:01:39

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 7'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:19', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:21', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:22', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:24', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:26', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:28', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'None (0)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:31', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered 'No (N)'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-08-02T18:03:33', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f5594fb0-9fb6-485f-a6dd-0f32227456d0' User entered '02 Aug 2020 18:03'	System	02 Aug 2020 22:03:35
	System	02 Aug 2020 22:03:35

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 21:40:23

US3122047

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:54:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:18

US3122047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '05 Aug 2020'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:18

US3122047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:18

US3122047

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:18

US3122047

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:40

US3122047

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	13 Aug 2020 14:42:40

US3122047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:56

US3122047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '10 Aug 2020'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:56

US3122047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:56

US3122047

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:42:56

US3122047

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	13 Aug 2020 14:43:43

US3122047

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	13 Aug 2020 14:43:43

US3122047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	19 Aug 2020 18:05:36

US3122047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18 Aug 2020'	(b) (4) Leah Corts (b) (4)	19 Aug 2020 18:05:36

US3122047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Leah Corts (b) (4)	19 Aug 2020 18:05:36

US3122047

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	19 Aug 2020 18:05:36

US3122047

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	19 Aug 2020 18:05:42

US3122047

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	19 Aug 2020 18:05:42

US3122047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:11:15

US3122047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Aug 2020'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:11:15

US3122047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:11:15

US3122047

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'VISIT2'	System	28 Aug 2020 13:11:15

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Pre-Dose (PREDOSE)'	Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Aug 2020'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17:10'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Aug 2020 17:10'	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '98.5' F	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '91'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'bpm'	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '15'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'breaths/min'	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '128'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '93'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Post-Dose (POSTDOSE)'	Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:12:28

US3122047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:03

US3122047

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Aug 2020'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:03

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:54:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:13:30

US3122047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:25

US3122047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Aug 2020'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:25

US3122047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17:54'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:25

US3122047

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Aug 2020 17:54'	System	28 Aug 2020 13:14:25

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '27 Aug 2020'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17:56'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '27 Aug 2020 17:56'	System	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered empty.	System	28 Aug 2020 13:14:52

US3122047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	28 Aug 2020 13:15:13

US3122047

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '1'	System	28 Aug 2020 13:15:13

US3122047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Brad Killebrew (b) (4)	21 Sep 2020 18:20:06

US3122047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '03 Sep 2020'	(b) (4) Brad Killebrew (b) (4)	21 Sep 2020 18:20:06

US3122047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brad Killebrew (b) (4)	21 Sep 2020 18:20:06

US3122047

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Brad Killebrew (b) (4)	21 Sep 2020 18:20:06

US3122047

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:34:46

US3122047

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	18 Sep 2020 18:34:46

US3122047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:03

US3122047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:03

US3122047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:03

US3122047

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:03

US3122047

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:07

US3122047

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	18 Sep 2020 18:35:07

US3122047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:22

US3122047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:22

US3122047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:22

US3122047

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:35:22

US3122047

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:36:01

US3122047

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	18 Sep 2020 18:36:01

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response "Resolved", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 16 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 08:35:50
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response "Resolved", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 16 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' answered with 'Pages added' (Site from DM).	Leah Corts (b) (4)	11 Feb 2021 19:57:10
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re-Query: Per response "Resolved", however there is no initiated Illness visit with corresponding SARS-CoV-2 serum sample dated 16 OCT 2020, please verify and update the data as needed, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 07:41:59
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 16 OCT 2020 as an illness Visit Day 1, 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)	11 Jan 2021 07:40:47
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 16 OCT 2020 as an illness Visit Day 1, but there is no record in EDC with this date. Please reconcile and update the data else clarify. ' answered with 'This is a duplicate query. Closing out and will update the query that other one when it has been completed. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:45:11

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample:Re-Query: It appears PPD central lab has a SARS-CoV-2 serum sample dated 16 OCT 2020 as an illness Visit Day 1, 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)	19 Nov 2020 05:01:10
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 16 OCT 2020 is reported under illness Visit Day 1 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).		19 Nov 2020 05:01:10
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 16 OCT 2020 is reported under illness Visit Day 1 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 'Resolved' (Site from DM).	Leah Corts (b) (4)	12 Nov 2020 15:26:48
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 16 OCT 2020 is reported under illness Visit Day 1 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)	29 Oct 2020 06:16:41
User entered 'Yes (Y)'	Leah Corts (b) (4)	06 Oct 2020 14:26:37

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 03:34:13
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'Resolved' (Site from DM).	Leah Corts (b) (4)	12 Nov 2020 15:26:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 16-Oct-2020 is reported under Illness Visit Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 07:11:10
User entered '05 Oct 2020'	Leah Corts (b) (4)	06 Oct 2020 14:26:37

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:26:37

US3122047

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'VISIT3'	System	06 Oct 2020 14:26:37

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '05 Oct 2020'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '14:16'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '05 Oct 2020 14:16'	System	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '98.1' F	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered empty.	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '101'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'bpm'	System	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '12'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'breaths/min'	System	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '128'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '88'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'mmHg'	System	06 Oct 2020 14:27:25

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29

US3122047

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29

US3122047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:24

US3122047

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered empty.	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:24

US3122047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:39

US3122047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '05 Oct 2020'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:39

US3122047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:32:29
User entered '15:42'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:39

US3122047

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered '05 Oct 2020 15:42'	System	06 Oct 2020 14:32:39

US3122047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	06 Oct 2020 14:32:44

US3122047

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	06 Oct 2020 14:32:44

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 64'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-09-26T01:07:33', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '36b9ede8-a7f7-4ff5-b45e-a9c20c569556'	System	26 Sep 2020 05:08:03
User entered 'No (N)'	System	26 Sep 2020 05:08:03

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-09-26T01:07:48', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '36b9ede8-a7f7-4ff5-b45e-a9c20c569556'	System	26 Sep 2020 05:08:03
User entered 'No (N)'	System	26 Sep 2020 05:08:03

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-09-26T01:08:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '36b9ede8-a7f7-4ff5-b45e-a9c20c569556' User entered '26 Sep 2020 01:08:00'	System	26 Sep 2020 05:08:03
	System	26 Sep 2020 05:08:03

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '26 Sep 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '30 Sep 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 71'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-03T01:19:25', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dced4a55-4972-4c8b-ac18-2ad0e4e92216' User entered 'No (N)'	System	03 Oct 2020 05:19:43
	System	03 Oct 2020 05:19:43

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-03T01:19:37', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dced4a55-4972-4c8b-ac18-2ad0e4e92216'	System	03 Oct 2020 05:19:43
User entered 'No (N)'	System	03 Oct 2020 05:19:43

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-03T01:19:42', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dced4a55-4972-4c8b-ac18-2ad0e4e92216' User entered '03 Oct 2020 01:19:42'	System	03 Oct 2020 05:19:43
	System	03 Oct 2020 05:19:43

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '03 Oct 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '07 Oct 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 78'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-10T11:20:09', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c661a3d8-b340-4fcd-abc7-e316baac7d88' User entered 'No (N)'	System	10 Oct 2020 15:20:21
	System	10 Oct 2020 15:20:21

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-10T11:20:01', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c661a3d8-b340-4fcd-abc7-e316baac7d88'	System	10 Oct 2020 15:20:21
User entered 'No (N)'	System	10 Oct 2020 15:20:21

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-10T11:20:17', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c661a3d8-b340-4fcd-abc7-e316baac7d88' User entered '10 Oct 2020 11:20:17'	System	10 Oct 2020 15:20:21
	System	10 Oct 2020 15:20:21

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '10 Oct 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '14 Oct 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 92'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-24T06:56:39', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f012e42e-916f-4419-a2da-f9c584024358'	System	24 Oct 2020 10:56:53
User entered 'No (N)'	System	24 Oct 2020 10:56:53

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-24T06:56:47', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f012e42e-916f-4419-a2da-f9c584024358'	System	24 Oct 2020 10:56:53
User entered 'No (N)'	System	24 Oct 2020 10:56:53

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-24T06:56:51', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f012e42e-916f-4419-a2da-f9c584024358' User entered '24 Oct 2020 06:56:51'	System	24 Oct 2020 10:56:53
	System	24 Oct 2020 10:56:53

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '24 Oct 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '28 Oct 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 99'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-31T00:24:50', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6f7bb04e-e751-4647-a4e6-75f8d35ea678' User entered 'No (N)'	System	31 Oct 2020 04:25:12
	System	31 Oct 2020 04:25:12

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-31T00:25:06', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6f7bb04e-e751-4647-a4e6-75f8d35ea678'	System	31 Oct 2020 04:25:12
User entered 'No (N)'	System	31 Oct 2020 04:25:12

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-10-31T00:25:10', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '6f7bb04e-e751-4647-a4e6-75f8d35ea678' User entered '31 Oct 2020 00:25:10'	System	31 Oct 2020 04:25:12
	System	31 Oct 2020 04:25:12

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '31 Oct 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '04 Nov 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 106'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-07T05:47:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '27536bd0-678c-4c27-9a4c-3e991b9c1e2b' User entered 'Yes (Y)'	System	07 Nov 2020 10:47:33
	System	07 Nov 2020 10:47:33

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-07T05:47:11', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '27536bd0-678c-4c27-9a4c-3e991b9c1e2b' User entered 'No (N)'	System	07 Nov 2020 10:47:33
	System	07 Nov 2020 10:47:33

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-07T05:47:17', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '27536bd0-678c-4c27-9a4c-3e991b9c1e2b' User entered 'No (N)'	System	07 Nov 2020 10:47:33
	System	07 Nov 2020 10:47:33

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-07T05:47:23', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '27536bd0-678c-4c27-9a4c-3e991b9c1e2b' User entered 'No (N)'	System	07 Nov 2020 10:47:33
	System	07 Nov 2020 10:47:33

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-07T05:47:31', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '27536bd0-678c-4c27-9a4c-3e991b9c1e2b' User entered '07 Nov 2020 05:47:31'	System	07 Nov 2020 10:47:33
	System	07 Nov 2020 10:47:33

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '07 Nov 2020 00:01'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '11 Nov 2020 23:59'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered 'Day 113'	System	28 Jul 2020 21:40:23

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-14T06:03:03', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c8e2040b-08f9-4a00-ae40-78656befa564'	System	14 Nov 2020 11:03:15
User entered 'No (N)'	System	14 Nov 2020 11:03:15

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-14T06:03:08', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c8e2040b-08f9-4a00-ae40-78656befa564'	System	14 Nov 2020 11:03:15
User entered 'No (N)'	System	14 Nov 2020 11:03:15

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-14T06:03:12', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'c8e2040b-08f9-4a00-ae40-78656befa564' User entered '14 Nov 2020 06:03:12'	System	14 Nov 2020 11:03:15
	System	14 Nov 2020 11:03:15

US3122047

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '14 Nov 2020 00:01'	System	28 Jul 2020 21:40:23

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:08:45
Data entry locked.	System	28 Jul 2020 21:40:23
User entered '18 Nov 2020 23:59'	System	28 Jul 2020 21:40:23

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:16:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:16:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-26T04:01:34', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9313b8c4-0cb8-4baa-9a75-54f39a223725' User entered 'No (N)'	System	26 Nov 2020 09:01:47
	System	26 Nov 2020 09:01:47

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-26T04:01:41', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9313b8c4-0cb8-4baa-9a75-54f39a223725' User entered 'No (N)'	System	26 Nov 2020 09:01:47
	System	26 Nov 2020 09:01:47

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-11-26T04:01:45', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9313b8c4-0cb8-4baa-9a75-54f39a223725' User entered '26 Nov 2020 04:01:45'	System	26 Nov 2020 09:01:47
	System	26 Nov 2020 09:01:47

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:16:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-02T06:14:26', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8e08780f-f962-4871-9e0d-9077cc7b9857'	System	02 Dec 2020 11:14:40
User entered 'No (N)'	System	02 Dec 2020 11:14:40

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-02T06:14:34', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8e08780f-f962-4871-9e0d-9077cc7b9857' User entered 'No (N)'	System	02 Dec 2020 11:14:40
	System	02 Dec 2020 11:14:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-02T06:14:36', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8e08780f-f962-4871-9e0d-9077cc7b9857' User entered '02 Dec 2020 06:14:36'	System	02 Dec 2020 11:14:40
	System	02 Dec 2020 11:14:40

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-09T04:28:49', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'aa92e2d3-a90a-4592-99d9-d0f39336cf4e' User entered 'No (N)'	System	09 Dec 2020 09:29:01
	System	09 Dec 2020 09:29:01

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-09T04:28:54', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'aa92e2d3-a90a-4592-99d9-d0f39336cf4e' User entered 'No (N)'	System	09 Dec 2020 09:29:01
	System	09 Dec 2020 09:29:01

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-09T04:28:58', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'aa92e2d3-a90a-4592-99d9-d0f39336cf4e' User entered '09 Dec 2020 04:28:58'	System	09 Dec 2020 09:29:01
	System	09 Dec 2020 09:29:01

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-16T00:33:22', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '0d0522b3-8c4a-46a1-8e00-c1446a301f99'	System	16 Dec 2020 05:34:02
User entered 'No (N)'	System	16 Dec 2020 05:34:02

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-16T00:33:41', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '0d0522b3-8c4a-46a1-8e00-c1446a301f99'	System	16 Dec 2020 05:34:02
User entered 'No (N)'	System	16 Dec 2020 05:34:02

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-16T00:33:57', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '0d0522b3-8c4a-46a1-8e00-c1446a301f99' User entered '16 Dec 2020 00:33:57'	System	16 Dec 2020 05:34:02
	System	16 Dec 2020 05:34:02

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-23T00:26:42', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8b9279b2-fd9f-4c9b-9efe-9cde056d2cd6' User entered 'No (N)'	System	23 Dec 2020 05:26:57
	System	23 Dec 2020 05:26:57

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-23T00:26:48', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8b9279b2-fd9f-4c9b-9efe-9cde056d2cd6'	System	23 Dec 2020 05:26:57
User entered 'No (N)'	System	23 Dec 2020 05:26:57

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58D400B7-C7FA-4E38-B6B1-FA719536C530)', Time: '2020-12-23T00:26:53', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '8b9279b2-fd9f-4c9b-9efe-9cde056d2cd6' User entered '23 Dec 2020 00:26:53'	System	23 Dec 2020 05:26:57
	System	23 Dec 2020 05:26:57

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-06T05:28:16', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e3fda626-d487-434e-b909-b5aa110df644'	System	06 Jan 2021 10:28:29
User entered 'No (N)'	System	06 Jan 2021 10:28:29

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-06T05:28:23', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e3fda626-d487-434e-b909-b5aa110df644'	System	06 Jan 2021 10:28:29
User entered 'No (N)'	System	06 Jan 2021 10:28:29

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-06T05:28:26', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'e3fda626-d487-434e-b909-b5aa110df644'	System	06 Jan 2021 10:28:29
User entered '06 Jan 2021 05:28:26'	System	06 Jan 2021 10:28:29

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-13T16:31:59', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7c4e73cd-b5fa-4f19-a720-e68d58c1c3dd' User entered 'No (N)'	System	13 Jan 2021 21:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-13T16:32:02', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7c4e73cd-b5fa-4f19-a720-e68d58c1c3dd'	System	13 Jan 2021 21:32:09
User entered 'No (N)'	System	13 Jan 2021 21:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-13T16:32:05', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7c4e73cd-b5fa-4f19-a720-e68d58c1c3dd' User entered '13 Jan 2021 16:32:05'	System	13 Jan 2021 21:32:09
	System	13 Jan 2021 21:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-20T00:17:30', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9109ca39-90cc-47b9-856a-9096d0e0d725'	System	20 Jan 2021 05:18:11
User entered 'No (N)'	System	20 Jan 2021 05:18:11

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-20T00:17:35', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9109ca39-90cc-47b9-856a-9096d0e0d725'	System	20 Jan 2021 05:18:11
User entered 'No (N)'	System	20 Jan 2021 05:18:11

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-20T00:17:37', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '9109ca39-90cc-47b9-856a-9096d0e0d725' User entered '20 Jan 2021 00:17:37'	System	20 Jan 2021 05:18:11
	System	20 Jan 2021 05:18:11

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-27T00:45:09', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7523d974-e58a-4216-ab95-7136cea4facc' User entered 'No (N)'	System	01 Feb 2021 14:53:49

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-27T00:45:19', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7523d974-e58a-4216-ab95-7136cea4facc' User entered 'No (N)'	System	01 Feb 2021 14:53:49

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-01-27T00:45:23', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7523d974-e58a-4216-ab95-7136cea4facc' User entered '27 Jan 2021 00:45:23'	System	01 Feb 2021 14:53:49
	System	01 Feb 2021 14:53:49

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-03T02:31:57', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5936161e-6548-4acb-b57c-884c130173a1' User entered 'No (N)'	System	03 Feb 2021 07:32:09
	System	03 Feb 2021 07:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-03T02:32:04', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5936161e-6548-4acb-b57c-884c130173a1' User entered 'No (N)'	System	03 Feb 2021 07:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-03T02:32:07', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5936161e-6548-4acb-b57c-884c130173a1' User entered '03 Feb 2021 02:32:07'	System	03 Feb 2021 07:32:09
	System	03 Feb 2021 07:32:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-10T00:29:55', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5d2626de-f23a-4335-a991-2d5ca9a2cd55'	System	10 Feb 2021 05:30:09
User entered 'No (N)'	System	10 Feb 2021 05:30:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-10T00:30:03', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5d2626de-f23a-4335-a991-2d5ca9a2cd55'	System	10 Feb 2021 05:30:09
User entered 'No (N)'	System	10 Feb 2021 05:30:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-10T00:30:06', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '5d2626de-f23a-4335-a991-2d5ca9a2cd55'	System	10 Feb 2021 05:30:09
User entered '10 Feb 2021 00:30:06'	System	10 Feb 2021 05:30:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-17T05:31:43', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dad8f221-f809-42fc-8010-375e1204a2d4'	System	17 Feb 2021 10:31:54
User entered 'No (N)'	System	17 Feb 2021 10:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-17T05:31:47', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dad8f221-f809-42fc-8010-375e1204a2d4' User entered 'No (N)'	System	17 Feb 2021 10:31:54
	System	17 Feb 2021 10:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-17T05:31:51', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'dad8f221-f809-42fc-8010-375e1204a2d4' User entered '17 Feb 2021 05:31:51'	System	17 Feb 2021 10:31:54
	System	17 Feb 2021 10:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-24T01:08:57-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7a099b85-0de2-4d49-9d16-aefd4de930c3' User entered 'No (N)'	System	24 Feb 2021 06:09:09
	System	24 Feb 2021 06:09:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-24T01:09:01-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7a099b85-0de2-4d49-9d16-aefd4de930c3'	System	24 Feb 2021 06:09:09
User entered 'No (N)'	System	24 Feb 2021 06:09:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-02-24T01:09:05-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '7a099b85-0de2-4d49-9d16-aefd4de930c3'	System	24 Feb 2021 06:09:09
User entered '24 Feb 2021 06:09:05'	System	24 Feb 2021 06:09:09

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-03T01:11:47-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b3664e5e-f72d-468e-8fdc-2c13312be436'	System	03 Mar 2021 06:11:56
User entered 'No (N)'	System	03 Mar 2021 06:11:56

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-03T01:11:50-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b3664e5e-f72d-468e-8fdc-2c13312be436'	System	03 Mar 2021 06:11:56
User entered 'No (N)'	System	03 Mar 2021 06:11:56

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-03T01:11:53-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b3664e5e-f72d-468e-8fdc-2c13312be436'	System	03 Mar 2021 06:11:56
User entered '03 Mar 2021 01:11:53'	System	03 Mar 2021 06:11:56

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-10T02:36:01-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '54b6da34-21e6-49a7-9273-d13020abbfa9' User entered 'No (N)'	System	10 Mar 2021 07:36:18
	System	10 Mar 2021 07:36:18

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-10T02:36:05-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '54b6da34-21e6-49a7-9273-d13020abbfa9'	System	10 Mar 2021 07:36:18
User entered 'No (N)'	System	10 Mar 2021 07:36:18

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-10T02:36:15-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '54b6da34-21e6-49a7-9273-d13020abbfa9' User entered '10 Mar 2021 02:36:15'	System	10 Mar 2021 07:36:18
	System	10 Mar 2021 07:36:18

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-17T05:18:24-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '46aab86a-b954-4434-99c3-dc18681aa539'	System	17 Mar 2021 09:18:35
User entered 'No (N)'	System	17 Mar 2021 09:18:35

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-17T05:18:28-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '46aab86a-b954-4434-99c3-dc18681aa539'	System	17 Mar 2021 09:18:35
User entered 'No (N)'	System	17 Mar 2021 09:18:35

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-17T05:18:31-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '46aab86a-b954-4434-99c3-dc18681aa539' User entered '17 Mar 2021 05:18:31'	System	17 Mar 2021 09:18:35
	System	17 Mar 2021 09:18:35

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-24T05:47:42-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f63eeea4-2001-45f4-9f86-c213dbb0db61'	System	24 Mar 2021 09:47:51
User entered 'No (N)'	System	24 Mar 2021 09:47:51

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-24T05:47:45-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f63eeea4-2001-45f4-9f86-c213dbb0db61'	System	24 Mar 2021 09:47:51
User entered 'No (N)'	System	24 Mar 2021 09:47:51

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-24T05:47:49-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'f63eeea4-2001-45f4-9f86-c213dbb0db61' User entered '24 Mar 2021 05:47:49'	System	24 Mar 2021 09:47:51
	System	24 Mar 2021 09:47:51

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-31T04:22:18-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b212e40c-4a77-4fb5-8bb8-3a2f8963e3b8'	System	31 Mar 2021 08:22:28
User entered 'No (N)'	System	31 Mar 2021 08:22:28

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-31T04:22:21-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b212e40c-4a77-4fb5-8bb8-3a2f8963e3b8' User entered 'No (N)'	System	31 Mar 2021 08:22:28
	System	31 Mar 2021 08:22:28

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-31T04:22:23-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'b212e40c-4a77-4fb5-8bb8-3a2f8963e3b8' User entered '31 Mar 2021 04:22:23'	System	31 Mar 2021 08:22:28
	System	31 Mar 2021 08:22:28

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-07T00:44:45-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '17093688-479f-46bb-ae7c-9ddd4b678873'	System	07 Apr 2021 04:44:58
User entered 'No (N)'	System	07 Apr 2021 04:44:58

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-07T00:44:49-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '17093688-479f-46bb-ae7c-9ddd4b678873'	System	07 Apr 2021 04:44:58
User entered 'No (N)'	System	07 Apr 2021 04:44:58

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-07T00:44:55-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '17093688-479f-46bb-ae7c-9ddd4b678873'	System	07 Apr 2021 04:44:58
User entered '07 Apr 2021 00:44:55'	System	07 Apr 2021 04:44:58

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-14T05:32:38-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'a8c81269-8bc1-4205-bcc7-c27b9cce69c6'	System	21 Apr 2021 09:31:54
User entered 'No (N)'	System	21 Apr 2021 09:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-14T05:32:42-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'a8c81269-8bc1-4205-bcc7-c27b9cce69c6'	System	21 Apr 2021 09:31:54
User entered 'No (N)'	System	21 Apr 2021 09:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-14T05:32:45-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: 'a8c81269-8bc1-4205-bcc7-c27b9cce69c6'	System	21 Apr 2021 09:31:54
User entered '14 Apr 2021 05:32:45'	System	21 Apr 2021 09:31:54

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-21T05:31:49-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3bce37a5-4883-4edb-bb71-b8f97170d58f' User entered 'No (N)'	System	21 Apr 2021 09:32:02
	System	21 Apr 2021 09:32:02

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-21T05:31:53-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3bce37a5-4883-4edb-bb71-b8f97170d58f' User entered 'No (N)'	System	21 Apr 2021 09:32:02
	System	21 Apr 2021 09:32:02

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-21T05:31:57-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '3bce37a5-4883-4edb-bb71-b8f97170d58f' User entered '21 Apr 2021 05:31:57'	System	21 Apr 2021 09:32:02
	System	21 Apr 2021 09:32:02

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-28T10:32:21-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '453cb872-5176-4035-b411-04a82701ce9b'	System	29 Apr 2021 01:40:31
User entered 'No (N)'	System	29 Apr 2021 01:40:31

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

Have you been exposed to someone with 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 (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-28T10:32:24-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '453cb872-5176-4035-b411-04a82701ce9b'	System	29 Apr 2021 01:40:31
User entered 'No (N)'	System	29 Apr 2021 01:40:31

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-04-28T10:32:26-04:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '453cb872-5176-4035-b411-04a82701ce9b'	System	29 Apr 2021 01:40:31
User entered '28 Apr 2021 10:32:26'	System	29 Apr 2021 01:40:31

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:16:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:16:32

US3122047

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:54:34

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:16:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:16:32

US3122047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:34

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)	30 Apr 2021 11:42:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-03T01:12:02-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '86669e10-11ca-4354-8f8a-a4269a928154'	System	03 Mar 2021 06:12:16
User entered 'No (N)'	System	03 Mar 2021 06:12:16

US3122047

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:54:34

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:42:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (68F1F65C-4718-4C7C-A7C8-A15A98C2B8EC)', Time: '2021-03-03T01:12:13-05:00', User OID: 'PatientReportedOutcome (US3122047)', ODM File OID: '86669e10-11ca-4354-8f8a-a4269a928154' User entered '03 Mar 2021 01:12:13'	System	03 Mar 2021 06:12:16
	System	03 Mar 2021 06:12:16

US3122047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:10:47

US3122047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:10:47

US3122047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:10:47

US3122047

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:10:47

US3122047

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:10:59

US3122047

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:27:29
User entered 'I'	System	18 Nov 2020 16:10:59

US3122047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:11:27

US3122047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "data updated"; however, corresponding swab sample of 16OCT2020 is missing in EDC. Kindly consider updating EDC for swab sample collected on 16OCT2020 by initiating and updating swab data in Covid Diagnosti Test eCRF under Covid-19 Assessment eCRF, else clarify.' (Site from DM).		25 Mar 2021 04:15:07
Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "data updated"; however, corresponding swab sample of 16OCT2020 is missing in EDC. Kindly consider updating EDC for swab sample collected on 16OCT2020 by initiating and updating swab data in Covid Diagnostic Test eCRF under Covid-19 Assessment eCRF, else clarify.' answered with 'updated' (Site from DM).		19 Mar 2021 19:02:57
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "data updated"; however, corresponding swab sample of 16OCT2020 is missing in EDC. Kindly consider updating EDC for swab sample collected on 16OCT2020 by initiating and updating swab data in Covid Diagnostic Test eCRF under Covid-19 Assessment eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 05:36:06
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16OCT2020 is reported under Illness 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).		26 Feb 2021 05:36:06
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 16OCT2020 is reported under Illness 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 'data updated' (Site from DM).	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:15:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)[illegible]

US3122047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:11:27

US3122047

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:11:27

US3122047

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:11:33

US3122047

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'I'	System	18 Nov 2020 16:11:33

US3122047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:32:05

US3122047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:32:05

US3122047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:32:05

US3122047

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:32:05

US3122047

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:25:35

US3122047

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'I'	System	03 Feb 2021 18:25:35

US3122047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:25:59

US3122047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).		24 Feb 2021 07:31:54
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' answered with 'data updated' (Site from DM).	(b) (4)	
	Leah Cortis (b) (4)	23 Feb 2021 20:13:18
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 16OCT2020 under Illness Visit Day 1 in PPD central lab, however same is missing in EDC. Please confirm and update the details under appropriate visit. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 05:18:15
User entered '3 Feb 2021'		03 Feb 2021 18:25:59

US3122047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:25:59

US3122047

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:25:59

US3122047

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:26:10

US3122047

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'I'	System	03 Feb 2021 18:26:10

US3122047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:10

US3122047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:10

US3122047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[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 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:10

US3122047

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'VISIT4'	System	12 Mar 2021 13:23:10

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '8 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '16:05'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered '8 Feb 2021 16:05'	System	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '90'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'bpm'	System	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'breaths/min'	System	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '141'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'mmHg'	System	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	31 Mar 2021 17:44:16
User entered '80'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'mmHg'	System	31 Mar 2021 14:33:32

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37

US3122047

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37

US3122047

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:35

US3122047

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:35

US3122047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:39

US3122047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:39

US3122047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:23:39

US3122047

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered empty.	System	12 Mar 2021 13:23:39

US3122047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:16

US3122047

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:10:37
User entered 'I'	System	12 Mar 2021 13:24:16

US3122047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:48:49

US3122047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:48:49

US3122047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:48:49

US3122047

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	25 Mar 2021 16:40:09
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:48:49

US3122047

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	26 Mar 2021 18:57:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 18:17:05

US3122047

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered 'I'	System	26 Mar 2021 18:17:05

US3122047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:10:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:51:50

US3122047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:10:06
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:51:50

US3122047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:10:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:51:50

US3122047

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:54:34

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 17:51:50

US3122047

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	26 Apr 2021 14:10:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 17:51:55

US3122047

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:54:34

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 17:51:55

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:34

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered '16 Oct 2020'	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:07:42

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:34

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered '13:30'	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:07:42

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:34

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User entered '16 Oct 2020 13:30'	System	23 Feb 2021 20:07:42

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:34

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:07:42

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:54:34

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
Signature has been broken.	(b) (4)	19 Mar 2021 18:47:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 18:47:39
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:07:42

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '99'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User entered '%'	System	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:54:34

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 18:51:39

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[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)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:54:34

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User entered '0'	System	19 Mar 2021 19:01:35

US3122047

Folder: Covid-19 Assessment 16 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:54:34

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:09:47
User signature succeeded.	Matthew Hong (b) (4)	23 Feb 2021 21:30:56
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	23 Feb 2021 20:09:24

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 3 (Day 3)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 5 (Day 5)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 7 (Day 7)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 9 (Day 9)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Feb 2021 19:53:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:53:54
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:53:49
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 14 (Day 14)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 21 (Day 21)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:54:34

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User accepted default value 'Day 28 (Day 28)'	Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:54:34

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:53:49

US3122047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '16 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[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 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Clinic (Clinic)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered 'SICKD1'	System	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '16 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '13:50'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered '16 Oct 2020 13:50'	System	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	11 Feb 2021 19:50:33
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Feb 2021 19:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:50:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 19:48:57
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:48:57
DataPoint set to visible.	System	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	11 Feb 2021 19:50:33
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Feb 2021 19:50:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:50:33
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 19:48:57
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:48:57
DataPoint set to visible.	System	11 Feb 2021 19:44:04

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '98.2' F	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Oral (Oral)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '94'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered 'bpm'	System	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered 'breaths/min'	System	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '134'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered 'mmHg'	System	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '97'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User entered 'mmHg'	System	11 Feb 2021 19:48:57

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02

US3122047

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02

US3122047

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:51:46

US3122047

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '16 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:51:46

US3122047

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:54:34

[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 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:52:05

US3122047

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:38:02
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '16 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:52:05

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:47

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:47

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:47

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	12 Mar 2021 13:24:47

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:54:34

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 13:24:53

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:57

US3122047

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:54:34

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:24:57

US3122047

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:54:34

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:25:02

US3122047

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 21:54:34

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	12 Mar 2021 17:20:40
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 13:25:02

US3122047

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08FEB2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' (Site from DM).		23 Apr 2021 14:31:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08FEB2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' answered with 'Request to unlock pages has been submitted to monitor' (Site from DM).		16 Apr 2021 20:21:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08FEB2021 is reported under visit 4 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under correct visit in EDC. ' (Site from DM).		16 Apr 2021 10:51:14
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:28

US3122047

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:28

US3122047

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:32:28

US3122047

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

Form: Visit Date

Generated On: 11 Aug 2021 21:54:34

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 20:32:28

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	09 Apr 2021 18:46:55
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:36:58
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:38:21

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). User signature succeeded.	(b) (4)	15 Apr 2021 01:26:04
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated.' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). Amendment Manager inserted this DataPoint.	Matthew Hong (b) (4) (b) (4) (b) (4), (b) (6)	09 Apr 2021 18:46:55 09 Apr 2021 13:37:17 09 Apr 2021 13:36:58 09 Apr 2021 11:24:53
	System	06 Mar 2021 10:38:21

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered empty.	System	21 Jan 2021 20:34:03

US3122047

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

Form: Unblinding

Generated On: 11 Aug 2021 21:54:34

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered empty.	System	21 Jan 2021 20:34:03

US3122047

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:23

US3122047

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:23

US3122047

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '15:20'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:23

US3122047

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered '21 Jan 2021 15:20'	System	21 Jan 2021 20:34:23

US3122047

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:40

US3122047

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:40

US3122047

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '15:23'	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:34:40

US3122047

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:36
User entered '21 Jan 2021 15:23'	System	21 Jan 2021 20:34:40

US3122047

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:54:34

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:34:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:17:13

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per DM CLR: Please review and reflect the type of RASH (Macular, Papular, etc); and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 03:32:55
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Rash urticarial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:57
Data point term sent to Coder	System	19 Nov 2020 17:20:20
Query 'Per DM CLR: Please review and reflect the type of RASH (Macular, Papular, etc); and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:20:14
Coding entries removed.		19 Nov 2020 17:19:58
User entered 'HYPERSENSITIVITY RASH - BILATERAL ELBOWS (Macular - Urticarial)' reason for change: Data Entry Error		19 Nov 2020 17:19:58
User closed query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).		28 Oct 2020 17:01:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Localized rash - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:29:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:29:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and reflect the type of RASH (Macular, Papular, etc); and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM). Data point term sent to Coder	(b) (4), (b) (6)	26 Oct 2020 10:05:34
Query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Clarified' (Site from DM).	System	23 Oct 2020 13:23:39
Coding entries removed.	Leah Corts (b) (4)	23 Oct 2020 13:23:13
User entered 'HYPERSENSITIVITY RASH - Bilateral Elbows' reason for change: Data Entry Error	Leah Corts (b) (4)	23 Oct 2020 13:23:05
User opened query 'Per DM CLR: Please specify the location if GENERALIZED or in specific area/s (e.g., BOTH ARMS, LEFT LEG, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:38:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis allergic, LLT: Allergic rash - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 20:31:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Sep 2020 20:31:37
Data point term sent to Coder	System	24 Aug 2020 14:19:37
User entered 'Hypersensitivity Rash'	Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:04:49
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' answered with 'corrected' (Site from DM).	Leah Corts (b) (4)	06 Oct 2020 14:37:19
User entered 'No (N)' reason for change: Data Entry Error	Leah Corts (b) (4)	06 Oct 2020 14:37:12
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 03:39:08
User entered 'Yes (Y)'	Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '04 Aug 2020'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User entered empty.	System	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '11 Aug 2020'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User entered empty.	System	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:21:06
User entered 'Related (RELATED)' reason for change: Data Entry Error	Leah Corts (b) (4)	24 Aug 2020 14:21:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:19:22
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:21:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leah Corts (b) (4)	24 Aug 2020 14:21:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:19:22
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User closed query 'Please update per our conversation the subject did not receive dose 2. ' (Site from CRA).		09 Mar 2021 22:28:32
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4)	11 Feb 2021 19:37:14
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	11 Feb 2021 19:37:14
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Dec 2020 20:26:27
Query 'Please update per our conversation the subject did not receive dose 2. ' answered with 'Corrected' (Site from CRA).	Leah Corts (b) (4)	04 Dec 2020 19:22:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution	Leah Corts (b) (4)	04 Dec 2020 19:22:28
User closed query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:09:14
User opened query 'Please update per our conversation the subject did not receive dose 2. ' (Site from CRA).		20 Nov 2020 21:09:16
Query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'Spoke with (b) (6) and determined the update' (Site from DM).		20 Nov 2020 20:59:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	20 Nov 2020 20:58:34
User opened query 'Per DM CLR: Action Taken with Investigational Product=Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).		26 Oct 2020 10:04:59
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' (Site from DM).		31 Aug 2020 12:45:15
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' answered with 'Visit 2 updated' (Site from DM).	Leah Corts (b) (4)	28 Aug 2020 13:16:01
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 03:20:39
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:21:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:21:06
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Leah Corts (b) (4)	24 Aug 2020 14:21:06
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:19:22
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'I'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 14:21:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Leah Corts (b) (4)	24 Aug 2020 14:21:06
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Aug 2020 14:19:22
User entered empty.	Leah Corts (b) (4)	24 Aug 2020 14:19:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User entered '0'	System	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52
User entered 'I'	System	24 Aug 2020 14:19:22

US3122047

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:21:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
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 Feb 2021 19:20:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:20:03
	(b) (4)	
Data point term sent to Coder	System	11 Feb 2021 19:19:35
User entered 'Depression'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '03 Nov 2020'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:42:40
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'ongoing' (Site from DM).		19 Mar 2021 19:24:05
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		02 Mar 2021 18:24:16
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'None (NONE)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

None

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	11 Feb 2021 19:19:35
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Feb 2021 19:19:25
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Thank you for the response. It was mentioned as updated for the concomitant medication taken for the event mentioned but there is no medication that matched with indication in the mentioned time frame. Kindly review and update.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:32:08
Query 'Per CDM: Thank you for the response. It was mentioned as updated for the concomitant medication taken for the event mentioned but there is no medication that matched with indication in the mentioned time frame. Kindly review and update.' answered with 'Relevant Conmed added.' (Site from DM).		24 Mar 2021 14:16:46
User opened query 'Per CDM: Thank you for the response. It was mentioned as updated for the concomitant medication taken for the event mentioned but there is no medication that matched with indication in the mentioned time frame. Kindly review and update.' (Site from DM).		22 Mar 2021 05:47:02
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		22 Mar 2021 05:42:55
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		19 Mar 2021 19:24:25
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 18:24:27
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '1' reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:19:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Leah Corts (b) (4)	11 Feb 2021 19:19:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 19:19:25

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:25:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:25:06
Data point term sent to Coder	System	11 Feb 2021 19:24:40
User entered 'Diarrhea'	Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '15 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User entered empty.	System	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	05 Apr 2021 18:55:26
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:47:34
User entered '18 Oct 2020' reason for change: Data Entry Error		01 Apr 2021 15:47:34
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '17 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User entered empty.	System	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'None (NONE)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed tha match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		22 Mar 2021 05:47:44
		19 Mar 2021 18:42:32
		02 Mar 2021 18:24:41
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'I'	Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User entered '0'	System	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01
User entered '0'	System	11 Feb 2021 19:23:45

US3122047

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:01

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:43:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:43:14
Data point term sent to Coder	System	11 Feb 2021 19:25:41
User entered 'Upper Respiratory Infection'	Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '15 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User entered empty.	System	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '22 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User entered empty.	System	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'None (NONE)'	Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		22 Mar 2021 05:47:58
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		19 Mar 2021 19:03:31
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		02 Mar 2021 18:24:59
User signature succeeded.		
User entered 'I'	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
	Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User entered '0'	System	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08
User entered '0'	System	11 Feb 2021 19:25:13

US3122047

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:08

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Pharyngitis, LLT: Pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:30:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Feb 2021 19:30:03
Data point term sent to Coder	System	11 Feb 2021 19:29:44
User entered 'Pharyngitis'	Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '14 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User entered empty.	System	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '18 Oct 2020'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User entered empty.	System	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'None (NONE)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

US3122047

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'I'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered '0'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered empty.	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User entered '0'	System	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15
User entered '0'	System	11 Feb 2021 19:29:02

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Folder: Adverse Events

Form: Adverse Events (5)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:22:15

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Borderline hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 19:24:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 19:24:51
Data point term sent to Coder	System	19 Mar 2021 19:24:13
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 19:23:38
Signature has been broken.		19 Mar 2021 19:23:38
User entered 'Borderline HYPERTENSION' reason for change: Data Entry Error		19 Mar 2021 19:23:38
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 18:23:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 18:23:01
User signature succeeded.	(b) (4)	
	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
Data point term sent to Coder	System	11 Feb 2021 19:30:45
User entered 'Potential Hypertension'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'Yes (Y)'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '03 Nov 2020'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:48:18
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'Ongoing' (Site from DM).		19 Mar 2021 19:23:48
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		02 Mar 2021 18:25:23
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Yes (Y)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered 'No (N)'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:31:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 19:31:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:31:49
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:30:44
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:31:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 19:31:49
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:31:49
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:30:44
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:31:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 19:31:49
User entered 'None (NONE)' reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:31:49
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 19:30:44
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:49:16
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).		19 Mar 2021 19:20:14
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		02 Mar 2021 18:25:39
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'I'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:30:44

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered '0'	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
	(b) (4)	
User entered empty.	Leah Corts (b) (4)	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Feb 2021 19:30:44

US3122047

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 21:54:34

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Feb 2021 19:30:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:54:34

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:34:07
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
Signature has been broken.	(b) (4)	19 Mar 2021 18:32:33
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 18:32:33
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'No (N)'	(b) (4)	19 Aug 2020 18:07:58
	Leah Corts (b) (4)	

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTO BISMOL [BISMUTH SUBSALICYLATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 18:37:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 18:37:35
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 18:37:17
User entered 'pepto bismol' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 18:36:36
User entered 'Peptobismal'		19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'Diarrhea'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '30'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '15 Oct 2020'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		02 Apr 2021 07:05:33
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Updated relevant AE end date.' (Site from DM).		01 Apr 2021 15:48:03
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		28 Mar 2021 07:27:58
User signature succeeded.		22 Mar 2021 15:04:23
User entered '18 Oct 2020'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User entered empty.	System	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User entered empty.	System	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:33:19
User entered empty.	System	19 Mar 2021 18:36:17

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 11:14:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 11:14:31
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	08 Apr 2021 15:23:04
Data point term sent to Coder	System	07 Apr 2021 21:05:41
User closed query 'DM-Coding: This medication GENERIC DAYQUIL cannot be referenced as reported. Please enter the active ingredient(s) with the drug name.	System	07 Apr 2021 21:05:18
' (Site from System).		
Query 'DM-Coding: This medication GENERIC DAYQUIL cannot be referenced as reported. Please enter the active ingredient(s) with the drug name.	(b) (4), (b) (6)	07 Apr 2021 21:05:18
' answered with 'It has been done' (Site from System)		
Signature has been broken.		07 Apr 2021 21:05:10
User entered 'GENERIC DAYQUIL (acetaminophen, phenylephrine HCl, dextromethorphan HBr)' reason for change: Data Entry Error		07 Apr 2021 21:05:10
User opened query 'DM-Coding: This medication GENERIC DAYQUIL cannot be referenced as reported. Please enter the active ingredient(s) with the drug name.	Coder Import (b) (4) (b) (4)	07 Apr 2021 13:59:30
' (Site from System).		
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	22 Mar 2021 15:04:23
Data point term sent to Coder	System	19 Mar 2021 18:41:24
User entered 'Generic Dayquil'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'Upper respiratory infection'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '30'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'other (OTHER)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'q4h'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
	(b) (4)	
User signature succeeded.	Matthew Hong (b) (4)	05 Apr 2021 18:55:26
	(b) (4)	
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:05:40
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'End date updated.' (Site from DM).		01 Apr 2021 15:50:24
Signature has been broken.		01 Apr 2021 15:50:11
User entered '22 Oct 2020' reason for change: Data Entry Error		01 Apr 2021 15:50:11
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		28 Mar 2021 07:28:11
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered '31 Oct 2020'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User entered empty.	System	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User entered empty.	System	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:34:01
User entered empty.	System	19 Mar 2021 18:41:09

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:36
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	22 Mar 2021 15:04:23
Data point term sent to Coder	System	19 Mar 2021 19:10:59
User entered 'Flu Zone'	(b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'flu prevention'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '1'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'shot'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '12 Sep 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Mar 2021 19:10:56

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:58:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:58:48
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	09 Apr 2021 18:46:55
Data point term sent to Coder	System	09 Apr 2021 14:16:07
User closed query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	09 Apr 2021 14:15:29
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Updated.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 14:15:29
Data point term sent to Coder	System	09 Apr 2021 14:15:05
Coding entries removed.	(b) (4), (b) (6)	09 Apr 2021 14:14:46
Signature has been broken.		09 Apr 2021 14:14:46
User entered 'GENERIC NYQUIL (Acetaminophen, Doxylamine succinate, Dextromethorphan HBr)' reason for change: Data Entry Error		09 Apr 2021 14:14:46
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4) (b) (4)	09 Apr 2021 09:54:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Name of Medication](#)

Audit	User	Time (GMT)
' (Site from System). User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;EPHEDRINE SULFATE;ETHANOL;PARACETAMOL, PRODUCTSYNONYM: NYQUIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 14:00:52
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	22 Mar 2021 15:04:23
Data point term sent to Coder	System	19 Mar 2021 19:16:05
User entered 'Generic Nyquil'	(b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Upper respiratory infection'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '30'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'qd'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	05 Apr 2021 18:55:26
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 07:05:49
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'End date updated.' (Site from DM).		01 Apr 2021 15:51:00
Signature has been broken.		01 Apr 2021 15:50:53
User entered '22 Oct 2020' reason for change: Data Entry Error		01 Apr 2021 15:50:53
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).		28 Mar 2021 07:28:28
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '31 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User entered empty.	System	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User entered empty.	System	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 10:37:06
User entered empty.	System	19 Mar 2021 19:15:44

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:27:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 13:27:27
User signature succeeded.	Matthew Hong (b) (4) (b) (4)	22 Mar 2021 15:04:23
Data point term sent to Coder	System	19 Mar 2021 19:20:10
User entered 'Losartan'	(b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Possible HTN'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '12.5'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	22 Mar 2021 15:04:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 19:19:35

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Mar 2021 14:17:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 14:17:36
Data point term sent to Coder	System	24 Mar 2021 14:16:41
User entered 'Zoloft'	(b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered '75'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	24 Mar 2021 18:29:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:54:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Mar 2021 14:16:04

US3122047

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:54:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Matthew Hong (b) (4)	10 Mar 2021 18:32:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:28:42

US3122047

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:34

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User closed query 'Per CDM: please confirm the date of dosing discontinuation. Thank You.' (Site from DM).	(b) (4)	(b) (4), (b) (6) 8 Dec 2020 17:48:17
Query 'Per CDM: please confirm the date of dosing discontinuation. Thank You.' answered with 'Confirmed' (Site from DM).		6 Dec 2020 21:16:47
User opened query 'Per CDM: please confirm the date of dosing discontinuation. Thank You.' (Site from DM).		6 Dec 2020 15:47:20
User entered '27 Aug 2020'		0 Dec 2020 20:26:27

US3122047

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:34

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4)	
reason for change: Data Entry Error	Leah Corts (b) (4)	11 Feb 2021 19:37:14
User entered 'Withdrawal of consent by participant	(b) (4), (b) (6)	10 Dec 2020 20:26:27
(specify) (WITHDRAWAL OF CONSENT)'		

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:54:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:56:07
User signature succeeded.	Matthew Hong (b) (4)	19 Feb 2021 20:31:12
User entered 'AE #1 - Participant choice.' reason for change: Data Entry Error	(b) (4) Leah Corts (b) (4)	11 Feb 2021 19:37:14
User entered 'Subject declined dose 2 due to AE.'	(b) (4), (b) (6)	10 Dec 2020 20:26:27