

US3092099 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:00:39

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US3092099

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

[Participant ID](#)

US3092099

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

US3092099

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Date of Birth (MMM yyyy)	(b) (6) 2001
Age	19
Age Units	YEARS
Age (Derived)	19
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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 00:39:40

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Date of Informed Consent (<i>dd MMM yyyy</i>)	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 00:39:40

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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 00:39:40

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:39:40

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:01 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:01
Height (<i>xxx.x</i>)	168.7 cm
Weight (<i>xxx.x</i>)	79.1 kg
BMI (<i>xxx.x</i>)	27.79370 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:39:40

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 00:39:40

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Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 00:39:40

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Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:39:40

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 00:39:40

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 00:39:40

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

What was the participant's randomization number? 102722

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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 00:39:40

Generated On: 11 Aug 2021 22:00:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 14:01
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 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 00:39:40

Generated On: 11 Aug 2021 22:00:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	16:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:27
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 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 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:54 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 15:54

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 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

15:50 (24 HR)

Collection date and time (derived)

10 AUG 2020 15:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:18	10 AUG 2020 15:18
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 10 AUG 2020 16:19

PC Open Date & Time 10 AUG 2020 16:14

PC Close Date & Time 10 AUG 2020 18:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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):

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

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

PC Time Stamp 11 AUG 2020 10:26

PC Open Date & Time 10 AUG 2020 19:39

PC Close Date & Time 11 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

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

12 AUG 2020 11:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 11:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 09:51

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 10:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

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

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

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 16:20

PC Open Date & Time

10 AUG 2020 16:14

PC Close Date & Time

10 AUG 2020 18:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 10:26

PC Open Date & Time

10 AUG 2020 19:39

PC Close Date & Time

11 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

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

12 AUG 2020 11:57

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

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

13 AUG 2020 11:01

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

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

14 AUG 2020 09:51

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

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

15 AUG 2020 10:46

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 16:20
PC Open Date & Time	10 AUG 2020 16:14
PC Close Date & Time	10 AUG 2020 18:44

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 10:27
PC Open Date & Time	10 AUG 2020 19:39
PC Close Date & Time	11 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 11:58
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

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 ☒

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 11:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

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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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 09:51
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 10:46
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

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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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

Yes ☐

PC Time stamp

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

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 ☒

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:08
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3092099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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)	9 SEP 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 11:32
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	9 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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?

US3092099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

12:27 (24 HR)

Collection date and time (derived)

9 SEP 2020 12:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:57	9 SEP 2020 11:57
Nasopharyngeal Swab 2	No		

US3092099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 13:45
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3092099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 NOV 2020

Collection time (00:00-23:59)

13:59 (24 HR)

Collection date and time (derived)

05 NOV 2020 13:59

US3092099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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	12 OCT 2020 13:59:38
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

17 OCT 2020 00:13:42

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 00:01:36

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

07 NOV 2020 00:01:23

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 01:35:36
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 NOV 2020 00:10:22

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 21:44:25
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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	11 DEC 2020 12:04:25
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

16 DEC 2020 15:28:29

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

27 DEC 2020 13:02:14

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

01 JAN 2021 12:06:20

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 17:00:54
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 JAN 2021 21:57:16
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 00:01:35
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 00:14:51

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 09:31:11
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

10 FEB 2021 10:15:10

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 FEB 2021 12:39:34
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

03 MAR 2021 04:51:31

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

13 MAR 2021 17:14:27

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 00:04:21
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 MAR 2021 00:02:19
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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	31 MAR 2021 00:05:49
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

07 APR 2021 10:07:49

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 09:19:17
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

21 APR 2021 00:38:57

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 00:18:07

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	_____
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 <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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 ☐

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 <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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 <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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 <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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 <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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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="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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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"/>

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3092099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:00:39

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 04:51:43

US3092099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:22:31

Generated On: 11 Aug 2021 22:00:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 02:22:17

Generated On: 11 Aug 2021 22:00:39

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) _____

US3092099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:22:31

Generated On: 11 Aug 2021 22:00:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3092099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Mar 2021 18:22:31

Generated On: 11 Aug 2021 22:00:39

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

Collection date (dd MMM yyyy)	26 FEB 2021
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Collection time (00:00-23:59)	14:19 (24 HR)
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Collection date and time (derived)	26 FEB 2021 14:19
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US3092099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:22:31

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 00:58:33

Generated On: 11 Aug 2021 22:00:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092099

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 00:58:33

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092099

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092099

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:00:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3092099

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

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

Visit date (dd MMM yyyy)	28 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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US3092099

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:43:15

Generated On: 11 Aug 2021 22:00:39

Date of updated informed consent (*dd MMM yyyy*) 28 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*) 28 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 _____

US3092099

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

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

Collection date (dd MMM yyyy)	28 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:29 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 JAN 2021 11:29
------------------------------------	-------------------

US3092099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

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

Collection date (dd MMM yyyy)	28 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:27
---------------------------------	-------

Collection Date and Time (derived)	28 JAN 2021 11:27
------------------------------------	-------------------

US3092099

Folder: Unscheduled (2)

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3092099

Folder: Unscheduled (3)

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 19 Feb 2021 00:39:40

Generated On: 11 Aug 2021 22:00:39

Visit Date	05 NOV 2020
------------	-------------

Please check all assessments that apply for this visit

Physical Exam	False
---------------	-------

Vital Signs	False
-------------	-------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	True
----------------	------

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Data signed: (b) (4) 29 Apr 2021 02:22:17

Generated On: 11 Aug 2021 22:00:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	05 NOV 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input checked="" type="radio"/>
	Negative <input type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3092099

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

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

Yes ☒

No ☐

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

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	10 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input 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"/>	

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Name of Medication PRENATAL VITAMINS

Prophylaxis Yes ☒
No ☐

Indication ABNORMAL/UNHEALTHY
PREGNANCY

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 ☐

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

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

US3092099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Mar 2021 18:22:31

Generated On: 11 Aug 2021 22:00:39

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3092099

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 19 Feb 2021 00:39:29

Generated On: 11 Aug 2021 22:00:39

Date of dosing discontinuation (dd MMM yyyy) 10 AUG 2020

Primary reason for dosing discontinuation

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

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

US3092099

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:00:39

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

US3092099 (Prod: Global Medical Research - M3 Wake Research)

US3092099

Form: Participant Creation

Generated On: 11 Aug 2021 22:00:39

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:21:37
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'US3092099'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:33

US3092099

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:52:20
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:32

US3092099

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:52:22
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:34

US3092099

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:52:46
User entered 'Clinic (Clinic)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:32

US3092099

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'SCRN'	System	10 Aug 2020 20:53:32

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:04
User entered (b) (6) 2001'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:35

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:06
User entered '19'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'YEARS'	System	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered '19'	System	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:15
User entered 'Female (F)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:26
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:31
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:33
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:34
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:36
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:37
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:42
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:44
User entered empty.	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:46
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:00:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:53:48
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:53:59

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:52
User entered '10 Aug 2020'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'Aug 2020'	System	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered '2020'	System	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:56:56
User entered 'Amendment 2 (2)' reason for change:	Vicki Martinez (b) (4)	11 Aug 2020 14:28:36
Data Entry Error	(b) (4)	
User entered 'Amendment 1 (1)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:24
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:29
User entered empty.	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:33
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:49

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:34

US3092099

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:00:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'I'	System	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:09:40
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:00:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:24
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:00:11

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:47
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:02:51
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:03:12
User entered '14:01'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered '10 Aug 2020 14:01'	System	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:03:19
User entered '168.7' cm	Robert Miranda (b) (4)	10 Aug 2020 21:01:58
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:03:23
User entered '79.1' kg	Robert Miranda (b) (4)	10 Aug 2020 21:01:58
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
Amendment Manager: User entered '27.79370'	System	16 Sep 2020 23:50:42
User entered '27.8'	System	10 Aug 2020 21:01:58
DataPoint set to visible.	System	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'kg/m2'	System	10 Aug 2020 21:01:58
DataPoint set to visible.	System	10 Aug 2020 20:54:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:35:31
User closed query 'Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. ' (Site from CRA).		25 Sep 2020 15:26:30
Query 'Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. ' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User opened query 'Please remove data for Temperature, Route of Measurement, Pulse, Respiratory, SBP, and DBP and update to "ND- Not Done" . Per eCRF guidelines for subjects screened/randomized/dosed same day, only Height and Weight is recorded under screening Vital Signs eCRF. ' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 23:10:31
User entered '37.1' C	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:06
User entered empty; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User entered 'Oral (Oral)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:08
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:35:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User entered '62'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'bpm'	System	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:35:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User entered '14'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'breaths/min'	System	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:35:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User entered '117'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'mmHg'	System	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:35:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:11
User entered '64'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered 'mmHg'	System	10 Aug 2020 21:01:58

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12

US3092099

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12

US3092099

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:08:10
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:02:50

US3092099

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:08:11
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:02:50

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:31
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:33
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:43
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:45
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:46
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:48
User entered '0'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:50
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:00:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:01:52
User entered '0'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:04:22

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:17
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:20
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:31
User entered 'Urine (URINE)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:38
User entered 'Negative (NEGATIVE)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:41
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:45
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:22:47
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User entered empty.	System	10 Aug 2020 21:07:44

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:48
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:49
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:51
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:55
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:57
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:57:58
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:00
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:03
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:05
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:06
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:10
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:12
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:13
User entered empty.	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '0'	Vicki Martinez (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:22
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:24
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:25
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:27
User entered 'I'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:30
User entered '0'	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '0'	Vicki Martinez (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:00:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:11:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 15:58:32
User entered empty.	Vicki Martinez (b) (4) (b) (4)	10 Aug 2020 20:56:47

US3092099

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:06:58
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:55

US3092099

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:00
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:55

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:01
User entered 'Clinic (Clinic)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:55

US3092099

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'VISIT1'	System	10 Aug 2020 21:11:55

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:07
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:25:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:25:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 20:14:38
User entered '102722' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:38

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:16
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:35
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:12:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:31
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:12:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:29
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:12:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:28
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:12:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:30:25
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:12:38

US3092099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
DataPoint Verified.		14 Apr 2021 19:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered 'No (N)'	(b) (4) Vicki Martinez (b) (4)	30 Oct 2020 17:26:32
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:16:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:21:11

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:13
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).		25 Sep 2020 15:26:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:20:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:19:57
User entered '1ND' (non-conformant).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 23:11:24
User entered '168.7' cm	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User entered '79.1' kg	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:13
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).		25 Sep 2020 15:26:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:20:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:19:57
User entered '1ND' (non-conformant).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 23:11:24
User entered '168.7' cm	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User entered '79.1' kg	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Pre-Dose (PREDOSE)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:21
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:27
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:30
User entered '14:01'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '10 Aug 2020 14:01'	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:34
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:47:16
User entered '37.1' C reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:36
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
User entered 'Oral (Oral)' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:39
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:42
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:47:16
User entered '62' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'bpm'	System	04 Sep 2020 13:47:16
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:48
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:47:16
User entered '14' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'breaths/min'	System	04 Sep 2020 13:47:16
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:54
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:47:16
User entered '117' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	04 Sep 2020 13:47:16
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:07:56
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:47:16
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:47:16
User entered '64' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:47:16
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	04 Sep 2020 13:47:16
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:13
User closed query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).		25 Sep 2020 15:26:42
Query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' answered with 'Updated' (Site from CRA).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:20:02
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:20:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 22:19:57
User entered '1ND' (non-conformant).	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User opened query 'Per eCRF Guidelines, Height and Weight should be marked as "ND"- Not Done under Visit 1 Day 1, for subject screened and randomized same day. Please update to ND for both' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 23:11:24
User entered '168.7' cm	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:00:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:16:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Heather Jimenez (b) (4) (b) (4)	24 Sep 2020 22:19:57
User entered '79.1' kg	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Post-Dose (POSTDOSE)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:20
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:22
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:29
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 03:24:58
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).		18 Aug 2020 20:56:10
User entered '16:27'	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '10 Aug 2020 16:27'	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:47
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:48:00
User entered '98.7' F reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:50
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:51
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:37:55
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:48:00
User entered '74' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'bpm'	System	04 Sep 2020 13:48:00
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:38:01
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:48:00
User entered '14' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'breaths/min'	System	04 Sep 2020 13:48:00
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:38:04
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:48:00
User entered '125' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	04 Sep 2020 13:48:00
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:38:06
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 13:48:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 13:48:00
User entered '71' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	04 Sep 2020 13:48:00
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:56:10
User entered empty.	Robert Miranda (b) (4) (b) (4)	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	04 Sep 2020 13:48:00
User entered empty.	System	18 Aug 2020 20:56:10

US3092099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:31:22
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:13:16

US3092099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:31:24
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:13:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:49:32
DataPoint Un-verified.	destiny robinson (b) (4)	20 Nov 2020 17:14:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) destiny robinson (b) (4)	20 Nov 2020 17:14:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:25:32
User closed query 'Per CDM: Screening and Visit1 Day1 are on the same day. Hence, as per the CCG please record the pregnancy test performed on VID1 as No and remove the other data to avoid the data duplication. Thank you. ' (Site from DM).		22 Oct 2020 09:16:47
Query 'Per CDM: Screening and Visit1 Day1 are on the same day. Hence, as per the CCG please record the pregnancy test performed on VID1 as No and remove the other data to avoid the data duplication. Thank you. ' answered with 'confirmed ' (Site from DM).	destiny robinson (b) (4) (b) (4)	22 Oct 2020 00:56:26
User entered 'No (N)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	22 Oct 2020 00:56:18
User opened query 'Per CDM: Screening and Visit1 Day1 are on the same day. Hence, as per the CCG please record the pregnancy test performed on VID1 as No and remove the other data to avoid the data duplication. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Sep 2020 10:00:23
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:49:33
DataPoint Un-verified.	destiny robinson (b) (4)	20 Nov 2020 17:14:38
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4) destiny robinson (b) (4)	20 Nov 2020 17:14:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:25:35
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:08
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4) (b) (4)	22 Oct 2020 00:56:08
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:49:35
DataPoint Un-verified.	destiny robinson (b) (4)	20 Nov 2020 17:14:38
User entered 'Urine (URINE)' reason for change:	(b) (4)	
Data Entry Error	destiny robinson (b) (4)	20 Nov 2020 17:14:38
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 16:25:37
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:08
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4)	22 Oct 2020 00:56:08
	(b) (4)	
User entered 'Urine (URINE)'	Robert Miranda (b) (4)	10 Aug 2020 21:17:16
	(b) (4)	

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:49:36
DataPoint Un-verified.	destiny robinson (b) (4)	20 Nov 2020 17:14:38
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4) destiny robinson (b) (4)	20 Nov 2020 17:14:38
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:25:38
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 00:56:08
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4) (b) (4)	22 Oct 2020 00:56:08
User entered 'Negative (NEGATIVE)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:49:38
User closed query 'Per CDM : Kindly confirm if the FSH sample collected is Yes/NO.Thanks ' (Site from DM).		23 Nov 2020 19:19:56
Query 'Per CDM : Kindly confirm if the FSH sample collected is Yes/NO.Thanks ' answered with 'was not done' (Site from DM).	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:14:57
DataPoint Un-verified.	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:14:38
User entered 'No (N)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:14:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:26:41
User opened query 'Per CDM : Kindly confirm if the FSH sample collected is Yes/NO.Thanks ' (Site from DM).		22 Oct 2020 09:17:23
User entered empty; reason for change Data Entry Error	destiny robinson (b) (4) (b) (4)	22 Oct 2020 00:56:08
User entered 'No (N)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:26:18
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:26:16
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	10 Aug 2020 21:17:16

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User closed query 'Per CDM: Per Diary Dose 1 Day 1, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Concomitant medication recorded that matches this information in the Concomitant medication eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:19:48
Query 'Per CDM: Per Diary Dose 1 Day 1, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Concomitant medication recorded that matches this information in the Concomitant medication eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' answered with 'will add' (Site from DM).	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:12:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 16:38:50
User opened query 'Per CDM: Per Diary Dose 1 Day 1, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Concomitant medication recorded that matches this information in the Concomitant medication eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' (Site from DM).		21 Sep 2020 05:35:38
Query 'Per CDM: Per Diary Dose 2 Day 1, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Concomitant medication recorded that matches this information in the Concomitant medication eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 05:35:22

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per Diary Dose 2 Day 1, To TREAT pain or fever that has already occurred= Yes, however, there is no corresponding Concomitant medication recorded that matches this information in the Concomitant medication eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. Thank you.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 05:19:32
	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:12
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:14
User entered empty.	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:45:19
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:47:12
User entered '15:54'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '10 Aug 2020 15:54'	System	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:47:14
User entered 'Left Arm (LEFT ARM)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
DataPoint Verified.		28 Oct 2020 16:47:15
User entered 'ONCE'	System	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 21:08:56

US3092099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:07:09
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:09:50

US3092099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:07:11
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:09:50

US3092099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:07:39
User entered '15:50'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:09:50

US3092099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '10 Aug 2020 15:50'	System	10 Aug 2020 21:09:50

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:00:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:57:18
User entered '10 Aug 2020'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:57:27
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:32:17
User closed query 'Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly. ' (Site from CRA).		17 Dec 2020 18:32:15
Query 'Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly. ' answered with 'done' (Site from CRA).	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:12:22
User entered '15:18' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:12:17
User opened query 'Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly. ' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 16:59:45
User entered '15:48'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '10 Aug 2020 15:18'	System	20 Nov 2020 17:12:17
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:32:22
DataPoint Un-verified.	destiny robinson (b) (4)	20 Nov 2020 17:11:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) destiny robinson (b) (4)	20 Nov 2020 17:11:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:08:45
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 18:32:24
User closed query ' Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly.' (Site from CRA).		17 Dec 2020 18:32:21
Query ' Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly.' answered with 'nd' (Site from CRA).	destiny robinson (b) (4)	20 Nov 2020 17:11:17
User entered empty; reason for change Data Entry Error	(b) (4)	20 Nov 2020 17:11:10
User opened query ' Nose Swab collection is noted in source as 15:18. Please verify which time is correct and revise accordingly.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 17:08:52
User entered '15:48'	Robert Miranda (b) (4)	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	20 Nov 2020 17:11:10
User entered '10 Aug 2020 15:48'	System	10 Aug 2020 21:11:15

US3092099

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:19:45
User entered 'Yes (Y)'	Robert Miranda (b) (4) (b) (4)	10 Aug 2020 21:11:21

US3092099

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	10 Aug 2020 21:11:21

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:14:45', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0e8d2eb0-c87e-4d9c-bfe6-0f674478750d' User entered 'Yes (Y)'	System	10 Aug 2020 21:19:27
	System	10 Aug 2020 21:19:27

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:12', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0e8d2eb0-c87e-4d9c-bfe6-0f674478750d' User entered '98.6'	System	10 Aug 2020 21:19:27
	System	10 Aug 2020 21:19:27

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0e8d2eb0-c87e-4d9c-bfe6-0f674478750d' User entered 'No (N)'	System	10 Aug 2020 21:19:27
	System	10 Aug 2020 21:19:27

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:24', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0e8d2eb0-c87e-4d9c-bfe6-0f674478750d' User entered '10 Aug 2020 16:19'	System	10 Aug 2020 21:19:27
	System	10 Aug 2020 21:19:27

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 16:14'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 18:44'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:03', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f' User entered 'Yes (Y)'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:06', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f' User entered '98.6'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:11', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f' User entered 'Yes (Y)'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:24', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f' User entered '0'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took IBU 200mg x1 for pain at injection site for 1 day. CLA' (Site from System).	(b) (4)	21 Sep 2020 05:17:47
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Catina Adams (b) (4)	10 Sep 2020 10:16:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:24', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f'	(b) (4)	
User entered '1'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:28', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '4c3d72c9-577f-479a-ab01-5c89dc17199f' User entered '11 Aug 2020 10:26'	System	11 Aug 2020 16:26:31
	System	11 Aug 2020 16:26:31

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 19:39'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 2'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:32', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5f7635ff-7ab7-47a8-a887-62b1ac5f026a' User entered 'Yes (Y)'	System	12 Aug 2020 16:57:44
	System	12 Aug 2020 16:57:44

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:35', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5f7635ff-7ab7-47a8-a887-62b1ac5f026a' User entered '97.6'	System	12 Aug 2020 16:57:44
	System	12 Aug 2020 16:57:44

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:38', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5f7635ff-7ab7-47a8-a887-62b1ac5f026a'	System	12 Aug 2020 16:57:44
User entered 'No (N)'	System	12 Aug 2020 16:57:44

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:40', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5f7635ff-7ab7-47a8-a887-62b1ac5f026a' User entered '12 Aug 2020 11:57'	System	12 Aug 2020 16:57:44
	System	12 Aug 2020 16:57:44

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 3'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:45', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '450abd00-3001-4759-92a3-ab972142226c' User entered 'Yes (Y)'	System	13 Aug 2020 16:00:57
	System	13 Aug 2020 16:00:57

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:49', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '450abd00-3001-4759-92a3-ab972142226c' User entered '98.7'	System	13 Aug 2020 16:00:57
	System	13 Aug 2020 16:00:57

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '450abd00-3001-4759-92a3-ab972142226c' User entered 'No (N)'	System	13 Aug 2020 16:00:57
	System	13 Aug 2020 16:00:57

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:53', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '450abd00-3001-4759-92a3-ab972142226c' User entered '13 Aug 2020 11:00'	System	13 Aug 2020 16:00:57
	System	13 Aug 2020 16:00:57

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 4'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:50:57', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9e703340-9b7a-4a01-a539-3df9bcc07f11' User entered 'Yes (Y)'	System	14 Aug 2020 14:51:14
	System	14 Aug 2020 14:51:14

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:01', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9e703340-9b7a-4a01-a539-3df9bcc07f11' User entered '96.7'	System	14 Aug 2020 14:51:14
	System	14 Aug 2020 14:51:14

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:07', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9e703340-9b7a-4a01-a539-3df9bcc07f11'	System	14 Aug 2020 14:51:14
User entered 'No (N)'	System	14 Aug 2020 14:51:14

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:11', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9e703340-9b7a-4a01-a539-3df9bcc07f11' User entered '14 Aug 2020 09:51'	System	14 Aug 2020 14:51:14
	System	14 Aug 2020 14:51:14

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 5'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:27', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0fefc593-d0bc-40da-8920-7f8cf7718ef9'	System	15 Aug 2020 15:46:37
User entered 'Yes (Y)'	System	15 Aug 2020 15:46:37

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:30', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0fefc593-d0bc-40da-8920-7f8cf7718ef9' User entered '98.7'	System	15 Aug 2020 15:46:37
	System	15 Aug 2020 15:46:37

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:32', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0fefc593-d0bc-40da-8920-7f8cf7718ef9'	System	15 Aug 2020 15:46:37
User entered 'No (N)'	System	15 Aug 2020 15:46:37

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0fefc593-d0bc-40da-8920-7f8cf7718ef9'	System	15 Aug 2020 15:46:37
User entered '15 Aug 2020 10:46'	System	15 Aug 2020 15:46:37

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 6'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 7'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:20', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '572630c9-9d63-4948-939a-39093b859625' User entered 'Yes (Y)'	System	16 Aug 2020 17:07:29
	System	16 Aug 2020 17:07:29

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:23', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '572630c9-9d63-4948-939a-39093b859625' User entered '98.7'	System	16 Aug 2020 17:07:29
	System	16 Aug 2020 17:07:29

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:26', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '572630c9-9d63-4948-939a-39093b859625'	System	16 Aug 2020 17:07:29
User entered 'No (N)'	System	16 Aug 2020 17:07:29

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:27', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '572630c9-9d63-4948-939a-39093b859625' User entered '16 Aug 2020 12:07'	System	16 Aug 2020 17:07:29
	System	16 Aug 2020 17:07:29

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8484f164-09fb-449f-a175-cca56c70fbae'	System	10 Aug 2020 21:20:10
User entered 'None (1)'	System	10 Aug 2020 21:20:10

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:46', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8484f164-09fb-449f-a175-cca56c70fbae'	System	10 Aug 2020 21:20:10
User entered 'No (N)'	System	10 Aug 2020 21:20:10

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:19:57', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8484f164-09fb-449f-a175-cca56c70fbae' User entered 'No (N)'	System	10 Aug 2020 21:20:10
	System	10 Aug 2020 21:20:10

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:04', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8484f164-09fb-449f-a175-cca56c70fbae'	System	10 Aug 2020 21:20:10
User entered 'None (1)'	System	10 Aug 2020 21:20:10

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:08', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8484f164-09fb-449f-a175-cca56c70fbae'	System	10 Aug 2020 21:20:10
User entered '10 Aug 2020 16:20'	System	10 Aug 2020 21:20:10

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 16:14'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 18:44'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject report taking IBU 200mg x1 for pain at injection site for 1 day. CLA' (Site from DM).		15 Oct 2020 06:49:40
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.'	Catina Adams (b) (4) (b) (4)	10 Sep 2020 10:15:59
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 16:10:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:47', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'ecc62651-dff8-4a78-9569-c12e2bbd2354'	System	11 Aug 2020 16:26:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	11 Aug 2020 16:26:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:49', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'ecc62651-dff8-4a78-9569-c12e2bbd2354' User entered 'No (N)'	System	11 Aug 2020 16:26:59
	System	11 Aug 2020 16:26:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:52', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'ecc62651-dff8-4a78-9569-c12e2bbd2354'	System	11 Aug 2020 16:26:59
User entered 'No (N)'	System	11 Aug 2020 16:26:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'ecc62651-dff8-4a78-9569-c12e2bbd2354'	System	11 Aug 2020 16:26:59
User entered 'None (1)'	System	11 Aug 2020 16:26:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:26:56', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'ecc62651-dff8-4a78-9569-c12e2bbd2354'	System	11 Aug 2020 16:26:59
User entered '11 Aug 2020 10:26'	System	11 Aug 2020 16:26:59

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 19:39'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 2'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:45', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'be39eb92-4ba8-4823-a553-1f38e8f7e916'	System	12 Aug 2020 16:58:03
User entered 'None (1)'	System	12 Aug 2020 16:58:03

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:48', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'be39eb92-4ba8-4823-a553-1f38e8f7e916' User entered 'No (N)'	System	12 Aug 2020 16:58:03
	System	12 Aug 2020 16:58:03

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'be39eb92-4ba8-4823-a553-1f38e8f7e916' User entered 'No (N)'	System	12 Aug 2020 16:58:03
	System	12 Aug 2020 16:58:03

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'be39eb92-4ba8-4823-a553-1f38e8f7e916'	System	12 Aug 2020 16:58:03
User entered 'None (1)'	System	12 Aug 2020 16:58:03

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:55', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'be39eb92-4ba8-4823-a553-1f38e8f7e916' User entered '12 Aug 2020 11:57'	System	12 Aug 2020 16:58:03
	System	12 Aug 2020 16:58:03

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 3'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:56', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '586efa91-5d68-4a67-9913-622e36aa8964'	System	13 Aug 2020 16:01:14
User entered 'None (1)'	System	13 Aug 2020 16:01:14

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:00:59', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '586efa91-5d68-4a67-9913-622e36aa8964' User entered 'No (N)'	System	13 Aug 2020 16:01:14
	System	13 Aug 2020 16:01:14

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '586efa91-5d68-4a67-9913-622e36aa8964' User entered 'No (N)'	System	13 Aug 2020 16:01:14
	System	13 Aug 2020 16:01:14

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:03', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '586efa91-5d68-4a67-9913-622e36aa8964'	System	13 Aug 2020 16:01:14
User entered 'None (1)'	System	13 Aug 2020 16:01:14

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:04', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '586efa91-5d68-4a67-9913-622e36aa8964' User entered '13 Aug 2020 11:01'	System	13 Aug 2020 16:01:14
	System	13 Aug 2020 16:01:14

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 4'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:14', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '083a5937-509d-490d-ab53-148b1677bb04'	System	14 Aug 2020 14:51:32
User entered 'None (1)'	System	14 Aug 2020 14:51:32

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '083a5937-509d-490d-ab53-148b1677bb04'	System	14 Aug 2020 14:51:32
User entered 'No (N)'	System	14 Aug 2020 14:51:32

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:23', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '083a5937-509d-490d-ab53-148b1677bb04'	System	14 Aug 2020 14:51:32
User entered 'No (N)'	System	14 Aug 2020 14:51:32

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:24', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '083a5937-509d-490d-ab53-148b1677bb04'	System	14 Aug 2020 14:51:32
User entered 'None (1)'	System	14 Aug 2020 14:51:32

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:29', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '083a5937-509d-490d-ab53-148b1677bb04' User entered '14 Aug 2020 09:51'	System	14 Aug 2020 14:51:32
	System	14 Aug 2020 14:51:32

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 5'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5031caf3-5a5d-483d-9840-7c8b85fab019'	System	15 Aug 2020 15:46:44
User entered 'None (1)'	System	15 Aug 2020 15:46:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:38', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5031caf3-5a5d-483d-9840-7c8b85fab019' User entered 'No (N)'	System	15 Aug 2020 15:46:44
	System	15 Aug 2020 15:46:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:39', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5031caf3-5a5d-483d-9840-7c8b85fab019' User entered 'No (N)'	System	15 Aug 2020 15:46:44
	System	15 Aug 2020 15:46:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:40', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5031caf3-5a5d-483d-9840-7c8b85fab019' User entered 'None (1)'	System	15 Aug 2020 15:46:44
	System	15 Aug 2020 15:46:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:42', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5031caf3-5a5d-483d-9840-7c8b85fab019' User entered '15 Aug 2020 10:46'	System	15 Aug 2020 15:46:44
	System	15 Aug 2020 15:46:44

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 6'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 7'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:32', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1bb2cae5-8e90-45ed-b449-c571eb832268'	System	16 Aug 2020 17:07:41
User entered 'None (1)'	System	16 Aug 2020 17:07:41

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1bb2cae5-8e90-45ed-b449-c571eb832268' User entered 'No (N)'	System	16 Aug 2020 17:07:41
	System	16 Aug 2020 17:07:41

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:35', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1bb2cae5-8e90-45ed-b449-c571eb832268' User entered 'No (N)'	System	16 Aug 2020 17:07:41
	System	16 Aug 2020 17:07:41

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1bb2cae5-8e90-45ed-b449-c571eb832268' User entered 'None (1)'	System	16 Aug 2020 17:07:41
	System	16 Aug 2020 17:07:41

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:38', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1bb2cae5-8e90-45ed-b449-c571eb832268' User entered '16 Aug 2020 12:07'	System	16 Aug 2020 17:07:41
	System	16 Aug 2020 17:07:41

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:18', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:21', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:24', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:26', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:27', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:29', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'None (0)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered 'No (N)'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-10T16:20:35', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e92e912b-1797-4eca-8f7d-9ff4bed87555'	System	10 Aug 2020 21:20:38
User entered '10 Aug 2020 16:20'	System	10 Aug 2020 21:20:38

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 16:14'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 18:44'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:01', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdf4ee7' User entered 'None (0)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:03', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7' User entered 'None (0)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:43', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7' User entered 'None (0)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:50', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7'	System	11 Aug 2020 16:28:04
User entered 'Some interference with activity (2)'	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:52', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7' User entered 'None (0)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdf4ee7' User entered 'None (0)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:57', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7' User entered 'No (N)'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-11T10:27:59', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7419930f-5bc2-4ca5-9cef-6a34cdcf4ee7' User entered '11 Aug 2020 10:27'	System	11 Aug 2020 16:28:04
	System	11 Aug 2020 16:28:04

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '10 Aug 2020 19:39'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 2'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:57:58', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:01', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:02', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:04', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:05', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'None (0)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:08', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered 'No (N)'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-12T11:58:10', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5e78b41d-8cf4-4786-8ffe-4cbd16567cbe' User entered '12 Aug 2020 11:58'	System	12 Aug 2020 16:58:12
	System	12 Aug 2020 16:58:12

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 3'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:07', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:08', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:09', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:10', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:11', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:13', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'None (0)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:14', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered 'No (N)'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-13T11:01:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0762ef4e-2091-410f-98ec-46783a54fc42'	System	13 Aug 2020 16:01:21
User entered '13 Aug 2020 11:01'	System	13 Aug 2020 16:01:21

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 4'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:39', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:40', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:41', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:43', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:44', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:46', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'None (0)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:48', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered 'No (N)'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-14T09:51:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '57a299dd-122d-4629-8496-25b91c79dfc3' User entered '14 Aug 2020 09:51'	System	14 Aug 2020 14:51:54
	System	14 Aug 2020 14:51:54

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 5'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:45', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:47', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:49', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:50', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:52', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:53', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'None (0)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered 'No (N)'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-15T10:46:55', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '923e7577-56b3-4e0f-806e-21eaf60c1ded' User entered '15 Aug 2020 10:46'	System	15 Aug 2020 15:46:57
	System	15 Aug 2020 15:46:57

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 6'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 7'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:53', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:55', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:56', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:57', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'None (0)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:07:59', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered 'No (N)'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-08-16T12:08:01', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'd87a738a-f84d-4047-a527-cb21d1a00190' User entered '16 Aug 2020 12:08'	System	16 Aug 2020 17:08:06
	System	16 Aug 2020 17:08:06

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 21:08:56

US3092099

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:00:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:22:21
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:32:58

US3092099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:22:35
User entered '18 Aug 2020'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:32:58

US3092099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:22:37
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:32:58

US3092099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:22:41
User entered empty.	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:32:58

US3092099

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:22:45
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:06

US3092099

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	28 Aug 2020 14:33:06

US3092099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:26:12
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:29

US3092099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:26:15
User entered '26 Aug 2020'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:29

US3092099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:26:17
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:29

US3092099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:26:18
User entered empty.	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:29

US3092099

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:26:21
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	28 Aug 2020 14:33:42

US3092099

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	28 Aug 2020 14:33:42

US3092099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:27:31
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	08 Sep 2020 17:12:47

US3092099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-Sep-2020 is reported under Visit 2 Day 29 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)	18 Nov 2020 12:24:51
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-Sep-2020 is reported under Visit 2 Day 29 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 'done' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 23:44:03
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 09-Sep-2020 is reported under Visit 2 Day 29 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 06:56:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:27:33
User entered '1 Sep 2020'	Catina Adams (b) (4) (b) (4)	08 Sep 2020 17:12:47

US3092099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:27:35
User entered 'Contact Made (CONTACT MADE)'	Catina Adams (b) (4) (b) (4)	08 Sep 2020 17:12:47

US3092099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:27:37
User entered empty.	Catina Adams (b) (4) (b) (4)	08 Sep 2020 17:12:47

US3092099

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit 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) (4), (b) (6)	24 Nov 2020 11:21:21
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit 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 'done' (Site from DM).	destiny robinson (b) (4) (b) (4)	20 Nov 2020 17:10:35
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:27:59
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 9SEP2020 is reported under Visit 2 Day 29visit 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).		21 Oct 2020 12:07:29
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	08 Sep 2020 17:12:07

US3092099

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '1'	System	08 Sep 2020 17:12:07

US3092099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:41:36
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:17:08

US3092099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:41:36
User entered '9 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:17:08

US3092099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:41:36
User entered 'Clinic (Clinic)' reason for change:	Vicki Martinez (b) (4)	30 Oct 2020 17:17:12
Data Entry Error	(b) (4)	
User entered 'Home (Home)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:17:08

US3092099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'VISIT2'	System	30 Oct 2020 17:17:08

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Pre-Dose (PREDOSE)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:41:57
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:01
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:30:14
User entered '9 Sep 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:30:14
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:18:55
User entered '9 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:03
User entered '11:32'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '9 Sep 2020 11:32'	System	30 Oct 2020 17:30:14
User entered '9 Oct 2020 11:32'	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:06
User entered '36.1' C	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:07
User entered 'Oral (Oral)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:09
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:13
User entered '76'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'bpm'	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:18
User entered '14'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'breaths/min'	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:20
User entered '110'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:42:22
User entered '74'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Post-Dose (POSTDOSE)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:10:30
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:00:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:18:55

US3092099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:47:08
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:19:34

US3092099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:47:08
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:19:39
User entered '9 Sep 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:19:39
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:19:34
User entered '9 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:19:34

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:20:12
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	30 Oct 2020 17:20:12
User entered '9 Sep 2020' reason for change: Data Entry Error	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:12
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	30 Oct 2020 17:20:03
User entered '9 Oct 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User entered 'Urine (URINE)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).		02 Nov 2020 07:07:29
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'Pregnancy test performed and confirmed pregnancy. Pregnancy form sent to IQVIA.' (Site from System).	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:00
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	30 Oct 2020 17:20:03
User entered 'Positive (POSITIVE)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:26
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:20:03

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered 'Pregnancy (PREGNANCY)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:11
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
DataPoint Verified.		28 Dec 2020 17:45:11
User entered empty.	System	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:00:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:21:27

US3092099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:52
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:48

US3092099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:52
User entered '9 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:48

US3092099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:45:52
User entered '12:27' reason for change: Data Entry Error	Vicki Martinez (b) (4)	30 Oct 2020 17:22:43
User entered '11:56'	(b) (4) Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:21:48

US3092099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '9 Sep 2020 12:27'	System	30 Oct 2020 17:22:43
User entered '9 Sep 2020 11:56'	System	30 Oct 2020 17:21:48

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:00:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:03
User entered '9 Sep 2020'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:03
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:03
User entered '11:57'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '9 Sep 2020 11:57'	System	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Vicki Martinez (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:03
User entered 'No (N)'	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:03
User entered empty.	Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered empty.	System	30 Oct 2020 17:22:30

US3092099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:46:07
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Nov 2020 23:41:05
User entered 'No (N)' reason for change: Data Entry Error	Vicki Martinez (b) (4)	30 Oct 2020 17:23:15
User entered 'Yes (Y)'	(b) (4) Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:23:06

US3092099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '1'	System	05 Nov 2020 23:41:05
User entered empty.	System	30 Oct 2020 17:23:15
User entered '1'	System	30 Oct 2020 17:23:06

US3092099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:27:30
User entered 'No (N)' reason for change: Data Entry Error		05 Nov 2020 23:54:14
User entered 'Yes (Y)'		05 Nov 2020 23:41:53

US3092099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:27:30
User entered empty; reason for change Data Entry Error		05 Nov 2020 23:54:14
User entered '18 Sep 2020'		05 Nov 2020 23:41:53

US3092099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:27:30
User entered empty; reason for change Data Entry Error		05 Nov 2020 23:54:14
User entered 'Contact Made (CONTACT MADE)'		05 Nov 2020 23:41:53

US3092099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:27:30
User entered empty.		05 Nov 2020 23:41:53

US3092099

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:15
User entered 'Yes (Y)'		05 Nov 2020 23:41:58

US3092099

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	05 Nov 2020 23:41:58

US3092099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:39
User entered 'No (N)' reason for change: Data Entry Error		05 Nov 2020 23:53:37
User entered 'Yes (Y)'		05 Nov 2020 23:42:28

US3092099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:39
User entered empty; reason for change Data Entry Error		05 Nov 2020 23:53:37
User entered '26 Aug 2020'		05 Nov 2020 23:42:28

US3092099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:39
User entered empty; reason for change Data Entry Error		05 Nov 2020 23:53:37
User entered 'Contact Made (CONTACT MADE)'		05 Nov 2020 23:42:28

US3092099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:39
User entered empty.		05 Nov 2020 23:42:28

US3092099

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:43
User entered 'Yes (Y)'		05 Nov 2020 23:42:44

US3092099

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	05 Nov 2020 23:42:44

US3092099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:48
User entered 'No (N)'		05 Nov 2020 23:42:52

US3092099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:48
User entered empty.		05 Nov 2020 23:42:52

US3092099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:48
User entered empty.		05 Nov 2020 23:42:52

US3092099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:48
User entered empty.		05 Nov 2020 23:42:52

US3092099

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:28:51
User entered 'Yes (Y)'		05 Nov 2020 23:45:57

US3092099

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	05 Nov 2020 23:45:57

US3092099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:33:57
User entered 'Yes (Y)'		05 Nov 2020 23:46:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:33:57
User entered '05 Nov 2020'		05 Nov 2020 23:46:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:33:57
User entered 'Clinic (Clinic)'		05 Nov 2020 23:46:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'VISIT3'	System	05 Nov 2020 23:46:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered 'Yes (Y)'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '05 Nov 2020'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '13:45'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '05 Nov 2020 13:45'	System	05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '98.0' F		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered 'Oral (Oral)'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered empty.		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '88'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'bpm'	System	05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '14'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'breaths/min'	System	05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '105'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:34:47
User entered '62'		05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'mmHg'	System	05 Nov 2020 23:47:28

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09

US3092099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09

US3092099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:28
User entered 'Yes (Y)'		05 Nov 2020 23:47:48

US3092099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:28
User entered '05 Nov 2020'		05 Nov 2020 23:47:48

US3092099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:38
User entered 'Yes (Y)'		05 Nov 2020 23:48:13

US3092099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:38
User entered '05 Nov 2020'		05 Nov 2020 23:48:13

US3092099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:38
User entered '13:59'		05 Nov 2020 23:48:13

US3092099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered '05 Nov 2020 13:59'	System	05 Nov 2020 23:48:13

US3092099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:35:48
User entered 'Yes (Y)'		05 Nov 2020 23:48:21

US3092099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	05 Nov 2020 23:48:21

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 64'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-12T13:59:34', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '99442342-7cd3-4dca-8233-ef8123281690' User entered 'No (N)'	System	12 Oct 2020 18:59:40
	System	12 Oct 2020 18:59:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-12T13:59:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '99442342-7cd3-4dca-8233-ef8123281690'	System	12 Oct 2020 18:59:40
User entered 'No (N)'	System	12 Oct 2020 18:59:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-12T13:59:38', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '99442342-7cd3-4dca-8233-ef8123281690' User entered '12 Oct 2020 13:59:38'	System	12 Oct 2020 18:59:40
	System	12 Oct 2020 18:59:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 71'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-17T00:13:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '42bc5d45-bd44-4a2b-afaa-5d4c7f650ec9' User entered 'No (N)'	System	17 Oct 2020 05:16:39
	System	17 Oct 2020 05:16:39

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-17T00:13:40', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '42bc5d45-bd44-4a2b-afaa-5d4c7f650ec9'	System	17 Oct 2020 05:16:39
User entered 'No (N)'	System	17 Oct 2020 05:16:39

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-17T00:13:42', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '42bc5d45-bd44-4a2b-afaa-5d4c7f650ec9' User entered '17 Oct 2020 00:13:42'	System	17 Oct 2020 05:16:39
	System	17 Oct 2020 05:16:39

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 78'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-24T00:01:31', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5dfb4777-d13e-4bf4-82ce-2d2342198ab4'	System	24 Oct 2020 05:01:40
User entered 'No (N)'	System	24 Oct 2020 05:01:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-24T00:01:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5dfb4777-d13e-4bf4-82ce-2d2342198ab4'	System	24 Oct 2020 05:01:40
User entered 'No (N)'	System	24 Oct 2020 05:01:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-10-24T00:01:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '5dfb4777-d13e-4bf4-82ce-2d2342198ab4' User entered '24 Oct 2020 00:01:36'	System	24 Oct 2020 05:01:40
	System	24 Oct 2020 05:01:40

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 92'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-07T00:01:17', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '6aee3b5f-0cde-4688-a372-55340a9cb4d0'	System	07 Nov 2020 06:02:50
User entered 'No (N)'	System	07 Nov 2020 06:02:50

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-07T00:01:21', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '6aee3b5f-0cde-4688-a372-55340a9cb4d0'	System	07 Nov 2020 06:02:50
User entered 'No (N)'	System	07 Nov 2020 06:02:50

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-07T00:01:23', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '6aee3b5f-0cde-4688-a372-55340a9cb4d0' User entered '07 Nov 2020 00:01:23'	System	07 Nov 2020 06:02:50
	System	07 Nov 2020 06:02:50

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered 'Day 99'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-14T01:35:31', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2f035696-d216-4c00-876f-fc069ead71c4'	System	14 Nov 2020 07:35:38
User entered 'No (N)'	System	14 Nov 2020 07:35:38

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-14T01:35:34', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2f035696-d216-4c00-876f-fc069ead71c4'	System	14 Nov 2020 07:35:38
User entered 'No (N)'	System	14 Nov 2020 07:35:38

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-14T01:35:36', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2f035696-d216-4c00-876f-fc069ead71c4' User entered '14 Nov 2020 01:35:36'	System	14 Nov 2020 07:35:38
	System	14 Nov 2020 07:35:38

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 21:08:56

US3092099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:41:25
Data entry locked.	System	10 Aug 2020 21:08:56
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 21:08:56

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-21T00:10:19', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '495400ed-763d-4dc6-a56d-2ff725366096' User entered 'No (N)'	System	21 Nov 2020 06:10:27

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-21T00:10:20', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '495400ed-763d-4dc6-a56d-2ff725366096'	System	21 Nov 2020 06:10:27
User entered 'No (N)'	System	21 Nov 2020 06:10:27

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-11-21T00:10:22', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '495400ed-763d-4dc6-a56d-2ff725366096' User entered '21 Nov 2020 00:10:22'	System	21 Nov 2020 06:10:27
	System	21 Nov 2020 06:10:27

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-05T21:44:20', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'af39aac2-e771-4351-9592-1fafbc136cfb' User entered 'No (N)'	System	06 Dec 2020 03:44:30
	System	06 Dec 2020 03:44:30

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-05T21:44:23', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'af39aac2-e771-4351-9592-1fafbc136cfb' User entered 'No (N)'	System	06 Dec 2020 03:44:30
	System	06 Dec 2020 03:44:30

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-05T21:44:25', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'af39aac2-e771-4351-9592-1fafbc136cfb' User entered '05 Dec 2020 21:44:25'	System	06 Dec 2020 03:44:30
	System	06 Dec 2020 03:44:30

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-11T12:04:21', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fc3135a2-9a81-413e-b37a-3e8ecddd6797'	System	11 Dec 2020 18:04:29
User entered 'No (N)'	System	11 Dec 2020 18:04:29

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-11T12:04:23', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fc3135a2-9a81-413e-b37a-3e8ecddd6797'	System	11 Dec 2020 18:04:29
User entered 'No (N)'	System	11 Dec 2020 18:04:29

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-11T12:04:25', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fc3135a2-9a81-413e-b37a-3e8ecddd6797'	System	11 Dec 2020 18:04:29
User entered '11 Dec 2020 12:04:25'	System	11 Dec 2020 18:04:29

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-16T15:28:25', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '25ee211d-60ad-4bb6-a2ac-32ad06dc6955' User entered 'No (N)'	System	16 Dec 2020 21:28:35
	System	16 Dec 2020 21:28:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-16T15:28:27', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '25ee211d-60ad-4bb6-a2ac-32ad06dc6955' User entered 'No (N)'	System	16 Dec 2020 21:28:35
	System	16 Dec 2020 21:28:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-16T15:28:29', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '25ee211d-60ad-4bb6-a2ac-32ad06dc6955' User entered '16 Dec 2020 15:28:29'	System	16 Dec 2020 21:28:35
	System	16 Dec 2020 21:28:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-27T13:02:10', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '06b504e3-57b9-4413-a30c-a510240eac8e' User entered 'No (N)'	System	27 Dec 2020 19:02:17
	System	27 Dec 2020 19:02:17

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-27T13:02:11', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '06b504e3-57b9-4413-a30c-a510240eac8e' User entered 'No (N)'	System	27 Dec 2020 19:02:17
	System	27 Dec 2020 19:02:17

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2020-12-27T13:02:14', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '06b504e3-57b9-4413-a30c-a510240eac8e' User entered '27 Dec 2020 13:02:14'	System	27 Dec 2020 19:02:17
	System	27 Dec 2020 19:02:17

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-01T12:06:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7611f69a-cb6d-4247-a677-b3de4b1d01de' User entered 'No (N)'	System	01 Jan 2021 18:06:22
	System	01 Jan 2021 18:06:22

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-01T12:06:18', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7611f69a-cb6d-4247-a677-b3de4b1d01de' User entered 'No (N)'	System	01 Jan 2021 18:06:22

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-01T12:06:20', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '7611f69a-cb6d-4247-a677-b3de4b1d01de' User entered '01 Jan 2021 12:06:20'	System	01 Jan 2021 18:06:22
	System	01 Jan 2021 18:06:22

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-07T17:00:48', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'caf47fb8-56cf-478d-9821-09d368a591bc' User entered 'No (N)'	System	07 Jan 2021 23:00:57

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-07T17:00:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'caf47fb8-56cf-478d-9821-09d368a591bc'	System	07 Jan 2021 23:00:57
User entered 'No (N)'	System	07 Jan 2021 23:00:57

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-07T17:00:54', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'caf47fb8-56cf-478d-9821-09d368a591bc' User entered '07 Jan 2021 17:00:54'	System	07 Jan 2021 23:00:57
	System	07 Jan 2021 23:00:57

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-16T21:57:12', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f7fd0da2-623c-49f5-8b58-0f52e65857a4'	System	17 Jan 2021 03:57:18
User entered 'No (N)'	System	17 Jan 2021 03:57:18

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-16T21:57:14', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f7fd0da2-623c-49f5-8b58-0f52e65857a4'	System	17 Jan 2021 03:57:18
User entered 'No (N)'	System	17 Jan 2021 03:57:18

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-16T21:57:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f7fd0da2-623c-49f5-8b58-0f52e65857a4' User entered '16 Jan 2021 21:57:16'	System	17 Jan 2021 03:57:18
	System	17 Jan 2021 03:57:18

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-20T00:01:31', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8ed9b581-f622-4ef9-b670-a084d7da3abb' User entered 'No (N)'	System	20 Jan 2021 06:01:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-20T00:01:33', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8ed9b581-f622-4ef9-b670-a084d7da3abb' User entered 'No (N)'	System	20 Jan 2021 06:01:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-20T00:01:35', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '8ed9b581-f622-4ef9-b670-a084d7da3abb' User entered '20 Jan 2021 00:01:35'	System	20 Jan 2021 06:01:46
	System	20 Jan 2021 06:01:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-27T00:14:16', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9234a008-7406-4510-a2a1-9a9ec6cf7a4a' User entered 'No (N)'	System	27 Jan 2021 06:14:54
	System	27 Jan 2021 06:14:54

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-27T00:14:17', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9234a008-7406-4510-a2a1-9a9ec6cf7a4a' User entered 'No (N)'	System	27 Jan 2021 06:14:54

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-01-27T00:14:51', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '9234a008-7406-4510-a2a1-9a9ec6cf7a4a' User entered '27 Jan 2021 00:14:51'	System	27 Jan 2021 06:14:54
	System	27 Jan 2021 06:14:54

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-03T09:31:08', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e44ce0ba-0de6-4971-b2b2-324fafce868a' User entered 'No (N)'	System	03 Feb 2021 15:31:14
	System	03 Feb 2021 15:31:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-03T09:31:09', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e44ce0ba-0de6-4971-b2b2-324fafce868a' User entered 'No (N)'	System	03 Feb 2021 15:31:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-03T09:31:11', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'e44ce0ba-0de6-4971-b2b2-324fafce868a' User entered '03 Feb 2021 09:31:11'	System	03 Feb 2021 15:31:14
	System	03 Feb 2021 15:31:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-10T10:15:06', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c8b9d0a3-04a5-460e-a4da-cbf142487832' User entered 'No (N)'	System	10 Feb 2021 16:15:14
	System	10 Feb 2021 16:15:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-10T10:15:07', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c8b9d0a3-04a5-460e-a4da-cbf142487832' User entered 'No (N)'	System	10 Feb 2021 16:15:14
	System	10 Feb 2021 16:15:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-10T10:15:10', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c8b9d0a3-04a5-460e-a4da-cbf142487832' User entered '10 Feb 2021 10:15:10'	System	10 Feb 2021 16:15:14
	System	10 Feb 2021 16:15:14

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-17T00:01:14', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0016d456-74a7-444b-85ae-dd3f0d6a62c7' User entered 'No (N)'	System	17 Feb 2021 06:01:26
	System	17 Feb 2021 06:01:26

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-17T00:01:15', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0016d456-74a7-444b-85ae-dd3f0d6a62c7' User entered 'No (N)'	System	17 Feb 2021 06:01:26
	System	17 Feb 2021 06:01:26

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-17T00:01:17', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '0016d456-74a7-444b-85ae-dd3f0d6a62c7' User entered '17 Feb 2021 00:01:17'	System	17 Feb 2021 06:01:26
	System	17 Feb 2021 06:01:26

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-24T06:39:27-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2b721028-06f7-427e-8811-16f1e9445471'	System	24 Feb 2021 12:39:37
User entered 'No (N)'	System	24 Feb 2021 12:39:37

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-24T06:39:31-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2b721028-06f7-427e-8811-16f1e9445471'	System	24 Feb 2021 12:39:37
User entered 'No (N)'	System	24 Feb 2021 12:39:37

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-02-24T06:39:34-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '2b721028-06f7-427e-8811-16f1e9445471'	System	24 Feb 2021 12:39:37
User entered '24 Feb 2021 12:39:34'	System	24 Feb 2021 12:39:37

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-03T04:51:26-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f56d3559-85e2-432f-89ab-94086e1904ba'	System	03 Mar 2021 10:51:34
User entered 'No (N)'	System	03 Mar 2021 10:51:34

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-03T04:51:28-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f56d3559-85e2-432f-89ab-94086e1904ba'	System	03 Mar 2021 10:51:34
User entered 'No (N)'	System	03 Mar 2021 10:51:34

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-03T04:51:31-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f56d3559-85e2-432f-89ab-94086e1904ba' User entered '03 Mar 2021 04:51:31'	System	03 Mar 2021 10:51:34
	System	03 Mar 2021 10:51:34

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-13T17:14:23-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f16a270e-1505-4820-8660-185367b37640'	System	13 Mar 2021 23:14:46
User entered 'No (N)'	System	13 Mar 2021 23:14:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-13T17:14:25-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f16a270e-1505-4820-8660-185367b37640'	System	13 Mar 2021 23:14:46
User entered 'No (N)'	System	13 Mar 2021 23:14:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-13T17:14:27-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f16a270e-1505-4820-8660-185367b37640' User entered '13 Mar 2021 17:14:27'	System	13 Mar 2021 23:14:46
	System	13 Mar 2021 23:14:46

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-17T00:04:14-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '60c20de9-f305-4714-ab4d-76b8b5992a40'	System	17 Mar 2021 05:04:45
User entered 'No (N)'	System	17 Mar 2021 05:04:45

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-17T00:04:16-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '60c20de9-f305-4714-ab4d-76b8b5992a40'	System	17 Mar 2021 05:04:45
User entered 'No (N)'	System	17 Mar 2021 05:04:45

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-17T00:04:21-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '60c20de9-f305-4714-ab4d-76b8b5992a40' User entered '17 Mar 2021 00:04:21'	System	17 Mar 2021 05:04:45
	System	17 Mar 2021 05:04:45

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-24T00:02:15-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1f3f7fd8-b374-476e-b4d4-8ef183eaa0af' User entered 'No (N)'	System	24 Mar 2021 05:02:28
	System	24 Mar 2021 05:02:28

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-24T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1f3f7fd8-b374-476e-b4d4-8ef183eaa0af'	System	24 Mar 2021 05:02:28
User entered 'No (N)'	System	24 Mar 2021 05:02:28

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-24T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1f3f7fd8-b374-476e-b4d4-8ef183eaa0af' User entered '24 Mar 2021 00:02:19'	System	24 Mar 2021 05:02:28
	System	24 Mar 2021 05:02:28

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-31T00:05:42-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '59d95eee-6d0d-4b97-ac0c-6731e0df9e84'	System	31 Mar 2021 05:05:55
User entered 'No (N)'	System	31 Mar 2021 05:05:55

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-31T00:05:45-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '59d95eee-6d0d-4b97-ac0c-6731e0df9e84'	System	31 Mar 2021 05:05:55
User entered 'No (N)'	System	31 Mar 2021 05:05:55

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-31T00:05:49-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '59d95eee-6d0d-4b97-ac0c-6731e0df9e84' User entered '31 Mar 2021 00:05:49'	System	31 Mar 2021 05:05:55
	System	31 Mar 2021 05:05:55

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-07T10:07:44-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'a75b55b5-9d14-452f-8d11-42d01b00bb70'	System	14 Apr 2021 16:46:35
User entered 'No (N)'	System	14 Apr 2021 16:46:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-07T10:07:46-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'a75b55b5-9d14-452f-8d11-42d01b00bb70'	System	14 Apr 2021 16:46:35
User entered 'No (N)'	System	14 Apr 2021 16:46:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-07T10:07:49-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'a75b55b5-9d14-452f-8d11-42d01b00bb70'	System	14 Apr 2021 16:46:35
User entered '07 Apr 2021 10:07:49'	System	14 Apr 2021 16:46:35

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-14T09:19:12-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c78b0d57-eee7-477a-9bc0-b871781a5fec'	System	14 Apr 2021 16:46:38
User entered 'No (N)'	System	14 Apr 2021 16:46:38

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-14T09:19:14-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c78b0d57-eee7-477a-9bc0-b871781a5fec'	System	14 Apr 2021 16:46:38
User entered 'No (N)'	System	14 Apr 2021 16:46:38

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-14T09:19:17-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'c78b0d57-eee7-477a-9bc0-b871781a5fec'	System	14 Apr 2021 16:46:38
User entered '14 Apr 2021 09:19:17'	System	14 Apr 2021 16:46:38

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-21T00:38:52-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f22dab67-8e16-4600-8a60-bfa9fc261ddc'	System	21 Apr 2021 05:39:00
User entered 'No (N)'	System	21 Apr 2021 05:39:00

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-21T00:38:55-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f22dab67-8e16-4600-8a60-bfa9fc261ddc'	System	21 Apr 2021 05:39:00
User entered 'No (N)'	System	21 Apr 2021 05:39:00

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-21T00:38:57-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'f22dab67-8e16-4600-8a60-bfa9fc261ddc'	System	21 Apr 2021 05:39:00
User entered '21 Apr 2021 00:38:57'	System	21 Apr 2021 05:39:00

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-28T00:18:02-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fa07a89e-2ee0-44ab-95a4-2fc586ac4d1a' User entered 'No (N)'	System	29 Apr 2021 06:13:32

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

Have you been exposed to someone with 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 (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-28T00:18:05-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fa07a89e-2ee0-44ab-95a4-2fc586ac4d1a'	System	29 Apr 2021 06:13:32
User entered 'No (N)'	System	29 Apr 2021 06:13:32

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-04-28T00:18:07-05:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: 'fa07a89e-2ee0-44ab-95a4-2fc586ac4d1a'	System	29 Apr 2021 06:13:32
User entered '28 Apr 2021 00:18:07'	System	29 Apr 2021 06:13:32

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:11:03

US3092099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:00:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:11:03
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:11:03

US3092099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:00:39

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)	25 Apr 2021 00:47:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-03T04:51:39-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1b53e3ea-cb1c-4258-a003-82e65a5ea104'	System	03 Mar 2021 10:51:46
User entered 'No (N)'	System	03 Mar 2021 10:51:46

US3092099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:00:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 00:47:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D480AFD5-0D22-4D33-840A-5981ACB5AE70)', Time: '2021-03-03T04:51:43-06:00', User OID: 'PatientReportedOutcome (US3092099)', ODM File OID: '1b53e3ea-cb1c-4258-a003-82e65a5ea104' User entered '03 Mar 2021 04:51:43'	System	03 Mar 2021 10:51:46
	System	03 Mar 2021 10:51:46

US3092099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:23:15
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	09 Nov 2020 20:34:39

US3092099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:23:15
User entered '6 Nov 2020'	Vicki Martinez (b) (4) (b) (4)	09 Nov 2020 20:34:39

US3092099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:23:15
User entered 'Contact Made (CONTACT MADE)'	Vicki Martinez (b) (4) (b) (4)	09 Nov 2020 20:34:39

US3092099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:23:15
User entered empty.	Vicki Martinez (b) (4) (b) (4)	09 Nov 2020 20:34:39

US3092099

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:23:22
User entered 'Yes (Y)'	Vicki Martinez (b) (4) (b) (4)	09 Nov 2020 20:34:46

US3092099

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:22:09
User entered 'I'	System	09 Nov 2020 20:34:46

US3092099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:17:23
User entered 'Yes (Y)'		07 Dec 2020 23:43:43

US3092099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:17:23
User entered '07 Dec 2020'		07 Dec 2020 23:43:43

US3092099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:17:23
User entered 'Contact Made (CONTACT MADE)'		07 Dec 2020 23:43:43

US3092099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:17:23
User entered empty.		07 Dec 2020 23:43:43

US3092099

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 18:17:28
User entered 'Yes (Y)'		07 Dec 2020 23:43:48

US3092099

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User entered 'I'	System	07 Dec 2020 23:43:48

US3092099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:11:26
User entered 'Yes (Y)'		05 Jan 2021 22:53:17

US3092099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:11:26
User entered '05 Jan 2021'		05 Jan 2021 22:53:17

US3092099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:11:26
User entered 'Contact Made (CONTACT MADE)'		05 Jan 2021 22:53:17

US3092099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:11:26
User entered empty.		05 Jan 2021 22:53:17

US3092099

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:11:30
User entered 'Yes (Y)'		05 Jan 2021 22:53:22

US3092099

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 05:07:41
User entered 'I'	System	05 Jan 2021 22:53:22

US3092099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
DataPoint Verified.		14 Apr 2021 18:06:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:02

US3092099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
DataPoint Verified.		14 Apr 2021 18:06:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered '03 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:02

US3092099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
DataPoint Verified.		14 Apr 2021 18:06:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:02

US3092099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
DataPoint Verified.		14 Apr 2021 18:06:53
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:02

US3092099

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
DataPoint Verified.		14 Apr 2021 18:06:57
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:41:08

US3092099

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:23
User entered 'I'	System	03 Feb 2021 21:41:08

US3092099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:14
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:21

US3092099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:14
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:21

US3092099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[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 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:14
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:21

US3092099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered 'VISIT4'	System	01 Mar 2021 23:34:21

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (D) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered 'No (N)'		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered empty.	System	14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered empty.	System	14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered empty.	System	14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered empty.	System	14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
Data hard locked.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 22:37:33
User entered empty.		14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered empty.	System	14 Apr 2021 22:31:48

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47

US3092099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:00:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47

US3092099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:35
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:29

US3092099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:00:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:35
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:29

US3092099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:44
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:45

US3092099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:44
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:45

US3092099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:44
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered '14:19'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:45

US3092099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered '26 Feb 2021 14:19'	System	01 Mar 2021 23:34:45

US3092099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
DataPoint Verified.		14 Apr 2021 18:08:47
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:34:50

US3092099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:23:47
User entered 'I'	System	01 Mar 2021 23:34:50

US3092099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:24

US3092099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:33
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:24

US3092099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:24

US3092099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:00:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:33
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:24

US3092099

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 00:58:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:26:07

US3092099

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:00:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 19:26:07

US3092099

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

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:18:57
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:18:53

US3092099

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

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:18:57
User entered '28 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:18:53

US3092099

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

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:18:57
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:18:53

US3092099

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

Form: Visit Date

Generated On: 11 Aug 2021 22:00:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 00:18:53

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered '28 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
DataPoint Verified.		14 Apr 2021 17:50:31
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:15
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:26:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:36:17

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
DataPoint Verified.		14 Apr 2021 17:50:29
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:43:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:26:05
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:36:17

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered '28 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered 'mRNA-1273 (mRNA-1273)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered 'mRNA-1273 (mRNA-1273)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered 'Not Administered (NA)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:05
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User entered empty.	System	29 Jan 2021 00:19:12

US3092099

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

Form: Unblinding

Generated On: 11 Aug 2021 22:00:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User entered empty.	System	29 Jan 2021 00:19:12

US3092099

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:16
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:27:50

US3092099

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:16
User entered '28 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:27:50

US3092099

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:19:16
User entered '11:29'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:27:50

US3092099

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User entered '28 Jan 2021 11:29'	System	29 Jan 2021 00:27:50

US3092099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:22:21
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:28:06

US3092099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:22:21
User entered '28 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:28:06

US3092099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:39

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 19:22:21
User entered '11:27'	Marissa Cervenka (b) (4) (b) (4)	29 Jan 2021 00:28:06

US3092099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:21:12
User entered '28 Jan 2021 11:27'	System	29 Jan 2021 00:28:06

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:54
DataPoint Verified.		16 Apr 2021 20:12:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '05 Nov 2020'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Dec 2020 20:44:24

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:54
DataPoint Verified.		16 Apr 2021 20:12:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Dec 2020 20:44:24

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:54
DataPoint Verified.		16 Apr 2021 20:12:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Dec 2020 20:44:24

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:54
DataPoint Verified.		16 Apr 2021 20:12:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered '0'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Dec 2020 20:44:24

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Unscheduled Visit Assessment

Generated On: 11 Aug 2021 22:00:39

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:54
DataPoint Verified.		16 Apr 2021 20:12:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:41
User entered 'I'	(b) (4) Vicki Martinez (b) (4) (b) (4)	11 Dec 2020 20:44:24

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered 'Yes (Y)'		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered '05 Nov 2020'		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered 'Urine (URINE)'		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
User closed query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:29:58
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:36:28
Query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' answered with 'ORIGINAL DATA CORRECT. SUBJECT TESTED POSITIVE. FORM HAS BEEN SUBMITTED TO IQVIA.' (Site from System).		14 Apr 2021 22:35:23
User opened query 'Pregnancy Test Result is POSITIVE for pregnancy test performed. Please confirm pregnancy test result was positive and submit a Pregnancy form to IQVIA (if one has not been submitted yet), or provide correct pregnancy test result.' (Site from System).	System	14 Apr 2021 22:33:52
User entered 'Positive (POSITIVE)'	(b) (4), (b) (6)	14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered 'No (N)'		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered empty.		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:22:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 22:36:28
User entered empty.		14 Apr 2021 22:33:52

US3092099

Folder: Unscheduled 05 Nov 2020

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:52:46
User entered empty.	System	14 Apr 2021 22:33:52

US3092099

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:00:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:14
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User closed query 'Per CDM: Did the participant experience any adverse events? = Yes; however, no AEs are recorded. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 05:27:23
Query 'Per CDM: Did the participant experience any adverse events? = Yes; however, no AEs are recorded. Please review and update as appropriate. ' answered with 'Data corrected' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	01 Dec 2020 16:38:06
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	01 Dec 2020 16:37:44
User opened query 'Per CDM: Did the participant experience any adverse events? = Yes; however, no AEs are recorded. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 09:14:11
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 20:56:36

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:00:39

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:15
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:39:08
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 20:57:43

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:39:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:01:43
Data point term sent to Coder	System	28 Sep 2020 21:00:57
User entered 'ibuprofen'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:39:26
User entered 'No (N)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:26
User entered 'pain at injection site'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:29
User entered '200'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:07
User entered 'mg (mg)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:09
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:01
User entered 'once daily (QD)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:47
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:44
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 21:00:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 21:00:24
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Shraddha Dubal (b) (4)	28 Sep 2020 21:00:24
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Sep 2020 21:00:09
User entered empty.	System	28 Sep 2020 21:00:09
	Shraddha Dubal (b) (4)	28 Sep 2020 21:00:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:45
User entered empty.	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:40:42
User entered '10 Aug 2020'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:14
User entered '0'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:15
User entered 'No (N)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:18
User entered '10 Aug 2020'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 16:41:53
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User entered '1'	System	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User entered '1'	System	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:00:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:47:08
User entered '804 (804)'	System	28 Sep 2020 21:00:09

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 06:09:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 06:09:48
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	19 Feb 2021 00:39:30
Data point term sent to Coder	System	03 Feb 2021 21:44:11
User entered 'prenatal vitamins'	(b) (4), (b) (6) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'abnormal/unhealthy pregnancy'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'un Jan 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered '0'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:24
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:00:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 21:43:20

US3092099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:00:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:21:40
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:22:31
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:33:54

US3092099

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:00:39

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:27
DataPoint Verified.	(b) (4)	14 Apr 2021 17:51:04
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered '10 Aug 2020' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	15 Dec 2020 21:58:36
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 23:42:59
User closed query 'Per CDM: Subject is tested positive for pregnancy at Visit 2 and Dose is not given. Kindly confirm and fill the "Dose Discontinuation" form and all the appropriate fields, else clarify. Thank you.' (Site from DM).	(b) (4)	22 Nov 2020 22:30:19
Query 'Per CDM: Subject is tested positive for pregnancy at Visit 2 and Dose is not given. Kindly confirm and fill the "Dose Discontinuation" form and all the appropriate fields, else clarify. Thank you.' answered with 'confirmed' (Site from DM).	destiny robinson (b) (4)	20 Nov 2020 17:17:22
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 17:16:57
User opened query 'Per CDM: Subject is tested positive for pregnancy at Visit 2 and Dose is not given. Kindly confirm and fill the "Dose Discontinuation" form and all the appropriate fields, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:29:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 10:26:15
Query 'Data is required. Please complete.' answered with 'confirm delete' (Site from System).	Vicki Martinez (b) (4)	09 Nov 2020 20:29:27
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 20:29:13
User entered empty; reason for change Data Entry Error	System	09 Nov 2020 20:29:13
User entered '9 Sep 2020'	Vicki Martinez (b) (4)	09 Nov 2020 20:29:13
	(b) (4)	30 Oct 2020 17:27:00

US3092099

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:00:39

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:38:27
DataPoint Verified.	(b) (4)	14 Apr 2021 17:51:06
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	(b) (4)	
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4)	15 Dec 2020 21:58:36
	(b) (4)	
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 23:42:59
	(b) (4)	
User entered 'Pregnancy (PREGNANCY)' reason for change: Data Entry Error	destiny robinson (b) (4)	20 Nov 2020 17:16:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 10:26:14
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'confirm delete' (Site from System).	Vicki Martinez (b) (4)	09 Nov 2020 20:29:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 20:29:13
User entered empty; reason for change Data Entry Error	Vicki Martinez (b) (4)	09 Nov 2020 20:29:13
	(b) (4)	
User entered 'Pregnancy (PREGNANCY)'	Vicki Martinez (b) (4)	30 Oct 2020 17:27:00
	(b) (4)	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:00:39

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 06:38:27
DataPoint Verified.		14 Apr 2021 17:51:08
User signature succeeded.	Valentine Ebuh (b) (4)	19 Feb 2021 00:39:30
User entered empty.	(b) (4) Vicki Martinez (b) (4) (b) (4)	30 Oct 2020 17:27:00