

US3092259 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:05:03

All time stamps listed in this document are displayed in GMT

US3092259

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 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 type="radio"/> Amendment 3 <input checked="" 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) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 03:45:22

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 03:45:22

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Condition	LOW TESTOSTERONE
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Condition	PRE - DIABETIC
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Condition	RENEL ALL CURCINOMA
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:05
Height (<i>xxx.x</i>)	184 cm
Weight (<i>xxx.x</i>)	103.7 kg
BMI (<i>xxx.x</i>)	30.62973 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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 03:45:22

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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) 23 Feb 2021 03:45:22

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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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109317

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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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)	28 AUG 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:05
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:42 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:42
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 12:09 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 12:09

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) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	11:55 (24 HR)
Collection date and time (derived)	28 AUG 2020 11:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	28 AUG 2020 11:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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: 09 Jun 2021 15:05:03

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 12:49

PC Open Date & Time

28 AUG 2020 12:29

PC Close Date & Time

28 AUG 2020 14:59

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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 98.2 °F

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

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

PC Time Stamp	28 AUG 2020 20:31
PC Open Date & Time	28 AUG 2020 15:54
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

29 AUG 2020 13:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

30 AUG 2020 19:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 17:16

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:37

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:57

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

28 AUG 2020 12:50

PC Open Date & Time

28 AUG 2020 12:29

PC Close Date & Time

28 AUG 2020 14:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

28 AUG 2020 20:32

PC Open Date & Time

28 AUG 2020 15:54

PC Close Date & Time

29 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

29 AUG 2020 13:25

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

30 AUG 2020 19:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

31 AUG 2020 17:16

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

01 SEP 2020 17:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:36

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

03 SEP 2020 19:57

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 12:51
PC Open Date & Time	28 AUG 2020 12:29
PC Close Date & Time	28 AUG 2020 14:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:32
PC Open Date & Time	28 AUG 2020 15:54
PC Close Date & Time	29 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

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)

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:25
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:48
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 17:16
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 17:59
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 16:37
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:58
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3092259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

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 _____

US3092259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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)	1 OCT 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 09:45
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:34
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 10:02 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:02

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

US3092259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	1 OCT 2020 09:58

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:54	1 OCT 2020 09:54
Nasopharyngeal Swab 2	No		

US3092259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

01 OCT 2020 10:25

PC Open Date & Time

01 OCT 2020 10:22

PC Close Date & Time

01 OCT 2020 12:52

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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 98.3 °F

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

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

PC Time Stamp	01 OCT 2020 20:05
PC Open Date & Time	01 OCT 2020 13:47
PC Close Date & Time	02 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 22:28

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

98.6 °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

03 OCT 2020 23:05

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 18:40

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

98.6 °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

05 OCT 2020 20:59

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

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

06 OCT 2020 17:27

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 19:44

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 10:24

PC Open Date & Time

01 OCT 2020 10:22

PC Close Date & Time

01 OCT 2020 12:52

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

01 OCT 2020 20:06

PC Open Date & Time

01 OCT 2020 13:47

PC Close Date & Time

02 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

02 OCT 2020 22:28

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

03 OCT 2020 23:06

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

04 OCT 2020 18:41

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

05 OCT 2020 20:58

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 17:27

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

07 OCT 2020 19:43

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:24
PC Open Date & Time	01 OCT 2020 10:22
PC Close Date & Time	01 OCT 2020 12:52

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 20:05
PC Open Date & Time	01 OCT 2020 13:47
PC Close Date & Time	02 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

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)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 22:29
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 23:06
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:41
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 20:58
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:27
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 19:43
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3092259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments VM 10/8/20...RETURNED CALL
10/8/20

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 10:00
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)	76 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)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3092259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	10:05 (24 HR)
Collection date and time (derived)	5 NOV 2020 10:05

US3092259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:22

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 14:50:48
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 22:00:43
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 DEC 2020 05:16:11
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 DEC 2020 19:39:04
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 09:24:27

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	27 DEC 2020 05:28:30
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 04:11:09
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

10 JAN 2021 04:28:17

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

17 JAN 2021 07:21:18

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	24 JAN 2021 09:47:30
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 JAN 2021 01:02:12
Patient Cloud Open Date & Time	31 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
131 of 2257	

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	07 FEB 2021 12:08:14
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 <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 13:03:14
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 08:23:06

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

28 FEB 2021 15:15:11

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	07 MAR 2021 09:31:20
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	14 MAR 2021 09:02:10
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

21 MAR 2021 08:01:35

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

28 MAR 2021 09:30:41

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 09:30:35

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	11 APR 2021 17:14:01
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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	18 APR 2021 06:53:02
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

25 APR 2021 09:32:00

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 10:22:16

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 278

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	05 AUG 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 369

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

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

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

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

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

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

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐ 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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	18 NOV 2021 23:59
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US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 <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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 474

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 <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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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 ☐ 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 ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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="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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

DAY 782

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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"/>

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3092259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:05:03

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		28 FEB 2021 15:15:21

US3092259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments 1ST ATTEMPT MADE ON
01/27/21
If Contact Not Made, please provide Comments 2ND ATTEMPT MADE ON
01/28/21
3RD ATTEMPT MADE ON
01/29/21

US3092259

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 APR 2021
Time of assessment (00:00-23:59)	08:15 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 08:15
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 APR 2021

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

US3092259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 APR 2021
Collection time (00:00-23:59)	08:43 (24 HR)
Collection date and time (derived)	13 APR 2021 08:43

US3092259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092259

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:05:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3092259

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

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

Visit date (dd MMM yyyy)	05 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3092259

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:52:46

Generated On: 09 Jun 2021 15:05:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	05 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	05 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3092259

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Height	184 cm
Weight	235 lb
BMI (xxx.x)	31.55074

US3092259

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Height	184 cm
Weight	235 lb
BMI (xxx.x)	31.55074
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)	05 JAN 2021
Time of assessment (00:00-23:59)	13:37 (24 HR)
Vital Signs Date and Time (derived)	05 JAN 2021 13:37
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Height	184 cm
Weight	235 lb
BMI (xxx.x)	31.55074
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)	05 JAN 2021
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	05 JAN 2021 14:17
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 JAN 2021

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

US3092259

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 05 JAN 2021

What was the treatment time? (00:00-23:59) 13:45 (24 HR)

Treatment Date and Time (derived) 05 JAN 2021 13:45

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

US3092259

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 JAN 2021
Collection time (00:00-23:59)	13:43 (24 HR)
Collection date and time (derived)	05 JAN 2021 13:43

US3092259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

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

Collection date (dd MMM yyyy)	05 JAN 2021
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Collection time (00:00 - 23:59)	13:41
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Collection Date and Time (derived)	05 JAN 2021 13:41
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US3092259

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:21

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

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)	05 FEB 2021
Time of assessment (00:00-23:59)	09:16 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 09:16
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	05 FEB 2021
Time of assessment (00:00-23:59)	10:21 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 10:21
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3092259

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3092259

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 05 FEB 2021

What was the treatment time? (00:00-23:59) 09:49 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 09:49

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

US3092259

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092259

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:50 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 10:50
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092259

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 MAR 2021

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

US3092259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 MAR 2021
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	1 MAR 2021 11:00

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Visit Date	05 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00-23:59)	09:46 (24 HR)
Collection date and time (derived)	05 FEB 2021 09:46

US3092259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

AEID

Adverse event

HEMATURIA DUE TO KIDNEY
STONES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

AEID

Adverse event

KIDNEY STONES

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

AEID	USA-US086-2021-MRNA-1273-P30 1000007
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	3 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

Number of Days in ICU	9
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3092259

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

SUBJECT STATES THAT HE WAS
HOSPITALIZED ON 25-JAN-2021
FOLLOWING PROCEDURE TO
REMOVE KIDNEY STONES
(22-JAN-2021. SUBJECT TO
OBTAIN A COPY OF MEDICAL
RECORDS AND CONMEDS AT
DISCHARGE AND WILL
PROVIDE A COPY TO THE SITE.
HE DOES NOT RECALL THE
MEDS HE IS TAKING BUT
KNOWS THAT HE IS RECEIVING
ANTIBIOTICS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

AEID

Adverse event

WORSENING OF INCONSISTENT
AND ELEVATED BLOOD
PRESSURE AND MED CHANGES
IN HOSPITAL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 22:38:20

Generated On: 09 Jun 2021 15:05:03

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

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 03:45:03

Generated On: 09 Jun 2021 15:05:03

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

Yes ☒

No ☐

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

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Name of Medication DEPO - TESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration .7

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Name of Medication TELMISARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Name of Medication WELCHOL

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 3760

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

367 of 2257

EAB) (1725)

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
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"/>

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 07 Mar 2021 18:32:49

Generated On: 09 Jun 2021 15:05:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 JAN 2021	KIDNEY STONE REMOVAL	Adverse Event	

US3092259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:05:03

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3092259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:05:03

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 ☐

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 16:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/FEB/2021 16:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/MAR/2021 14:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/MAR/2021 13:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 14 Apr 2021 01:04:13

Generated On: 09 Jun 2021 15:05:03

SAEID	USA-US086-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VALENTINE
Investigator's Last Name	EBUH
Site Address: Street	2701 S HAMPTON ROAD, SUITE 250
Site Address: City	DALLAS
Site Address: State	TX
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/APR/2021 13:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3092259 (Prod: Global Medical Research - M3 Wake Research)

US3092259

Form: Participant Creation

Generated On: 09 Jun 2021 15:05:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'US3092259'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:44:54

US3092259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:16:59

US3092259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:44:54

US3092259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Clinic (Clinic)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:16:59

US3092259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'SCRN'	System	28 Aug 2020 17:16:59

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:44:55

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '58'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'YEARS'	System	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '58'	System	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Male (M)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'I'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:05:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:20

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Aug 2020'	System	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2020'	System	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 20:40:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 20:40:12
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	destiny robinson (b) (4)	23 Nov 2020 20:40:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Aug 2020 17:17:39
User entered empty.	System	28 Aug 2020 17:17:39
	Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39
	(b) (4)	

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:17:39

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:44:54

US3092259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:05:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'I'	System	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:05:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:50:21

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User coded data point as SOC: Investigations, HLGHT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:52:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:52:23
Data point term sent to Coder	System	05 Nov 2020 16:51:45
User entered 'low testosterone'	(b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2012'	System	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2012'	System	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:51:04

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:52:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:52:22
Data point term sent to Coder	System	05 Nov 2020 16:51:45
User entered 'hypertension'	(b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2005'	System	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2005'	System	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:51:38

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 17:09:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 17:09:20
Data point term sent to Coder	System	05 Nov 2020 16:52:46
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2005'	System	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2005'	System	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered empty.	System	05 Nov 2020 16:52:07

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 11:10:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:10:21
Data point term sent to Coder	System	05 Nov 2020 16:53:48
User entered 'Pre - Diabetic'	(b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2018'	System	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2018'	System	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2019'	System	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2019'	System	05 Nov 2020 16:53:18

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Renal carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Nov 2020 12:45:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:45:04
Data point term sent to Coder	System	05 Nov 2020 16:54:50
User entered 'renal all carcinoma'	(b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'un UNK 2002'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'UN UNK 2002'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2002'	System	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2002'	System	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'Jan 2002'	System	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '2002'	System	05 Nov 2020 16:54:28

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '11:05'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '28 Aug 2020 11:05'	System	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '184' cm	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25
DataPoint set to visible.	System	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '103.7' kg	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25
DataPoint set to visible.	System	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered '30.62973'	System	05 Nov 2020 16:56:25
DataPoint set to visible.	System	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'kg/m2'	System	05 Nov 2020 16:56:25
DataPoint set to visible.	System	28 Aug 2020 17:18:36

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'bpm'	System	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'breaths/min'	System	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'mmHg'	System	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User entered 'mmHg'	System	05 Nov 2020 16:56:25

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48

US3092259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48

US3092259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:00

US3092259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:59:00

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'I'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:05:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:57:48
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:19:15

US3092259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1visit 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 10:53:13
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1visit 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)	23 Nov 2020 20:40:24
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28AUG2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:44:14
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:19:24

US3092259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 28-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 10:30:11
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 28-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'done ' (Site from DM).	destiny robinson (b) (4) (b) (4)	23 Nov 2020 20:40:28
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:36:43
User entered '28 Aug 2020'	Shraddha Dubal (b) (4) (b) (4)	28 Aug 2020 17:19:24

US3092259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Clinic (Clinic)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:19:24

US3092259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'VISIT1'	System	28 Aug 2020 17:19:24

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:09:27

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '109317'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:09:27

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:09:27

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:01:52
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'answer is no' (Site from DM).	destiny robinson (b) (4) (b) (4)	23 Nov 2020 20:41:14
User entered 'No (N)'	destiny robinson (b) (4) (b) (4)	23 Nov 2020 20:40:46
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 13:42:00

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	23 Nov 2020 20:40:46

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	destiny robinson (b) (4)	23 Nov 2020 20:40:46

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	destiny robinson (b) (4)	23 Nov 2020 20:40:46

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) destiny robinson (b) (4)	23 Nov 2020 20:40:46

US3092259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) destiny robinson (b) (4)	23 Nov 2020 20:40:46
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:40:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:28:29

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Pre-Dose (PREDOSE)'		05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '11:05'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '28 Aug 2020 11:05'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '87'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'bpm'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '14'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'breaths/min'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '108'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '77'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Post-Dose (POSTDOSE)'		05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '12:42'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '28 Aug 2020 12:42'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '83'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'bpm'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'breaths/min'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '106'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '78'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 17:04:37

US3092259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:06:27

US3092259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:06:27

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '12:09'	Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '28 Aug 2020 12:09'	System	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Left Arm (LEFT ARM)'	Shraddha Dubal (b) (4)	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'ONCE'	System	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 17:20:47

US3092259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:07:51

US3092259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:07:51

US3092259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '11:55'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:07:51

US3092259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '28 Aug 2020 11:55'	System	05 Nov 2020 17:07:51

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '11:50'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '28 Aug 2020 11:50'	System	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered empty.	System	05 Nov 2020 17:08:25

US3092259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	28 Aug 2020 17:20:57

US3092259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	28 Aug 2020 17:20:57

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:49:26', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a0a16f17-79fa-4449-a7dd-c835ed6b6f5e' User entered 'Yes (Y)'	System	28 Aug 2020 17:50:31
	System	28 Aug 2020 17:50:31

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:49:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a0a16f17-79fa-4449-a7dd-c835ed6b6f5e' User entered '97.6'	System	28 Aug 2020 17:50:31
	System	28 Aug 2020 17:50:31

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:49:51', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a0a16f17-79fa-4449-a7dd-c835ed6b6f5e' User entered 'No (N)'	System	28 Aug 2020 17:50:31
	System	28 Aug 2020 17:50:31

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:49:58', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a0a16f17-79fa-4449-a7dd-c835ed6b6f5e' User entered '28 Aug 2020 12:49'	System	28 Aug 2020 17:50:31
	System	28 Aug 2020 17:50:31

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 12:29'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 14:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:20', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ae3242ea-2415-4f60-a06a-0a23498712b5' User entered 'Yes (Y)'	System	29 Aug 2020 01:31:43
	System	29 Aug 2020 01:31:43

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ae3242ea-2415-4f60-a06a-0a23498712b5' User entered '98.2'	System	29 Aug 2020 01:31:43
	System	29 Aug 2020 01:31:43

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:34', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ae3242ea-2415-4f60-a06a-0a23498712b5' User entered 'No (N)'	System	29 Aug 2020 01:31:43
	System	29 Aug 2020 01:31:43

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ae3242ea-2415-4f60-a06a-0a23498712b5' User entered '28 Aug 2020 20:31'	System	29 Aug 2020 01:31:43
	System	29 Aug 2020 01:31:43

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 15:54'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 2'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00891f84-7474-44af-b18f-dfa8a48dcf35'	System	29 Aug 2020 18:25:28
User entered 'Yes (Y)'	System	29 Aug 2020 18:25:28

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00891f84-7474-44af-b18f-dfa8a48dcf35' User entered '97.6'	System	29 Aug 2020 18:25:28
	System	29 Aug 2020 18:25:28

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:20', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00891f84-7474-44af-b18f-dfa8a48dcf35'	System	29 Aug 2020 18:25:28
User entered 'No (N)'	System	29 Aug 2020 18:25:28

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:24', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00891f84-7474-44af-b18f-dfa8a48dcf35'	System	29 Aug 2020 18:25:28
User entered '29 Aug 2020 13:25'	System	29 Aug 2020 18:25:28

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 3'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e4da9f15-4a9f-4346-aa09-3c9485ed0594' User entered 'Yes (Y)'	System	31 Aug 2020 00:47:39
	System	31 Aug 2020 00:47:39

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:31', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e4da9f15-4a9f-4346-aa09-3c9485ed0594' User entered '97.7'	System	31 Aug 2020 00:47:39
	System	31 Aug 2020 00:47:39

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:34', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e4da9f15-4a9f-4346-aa09-3c9485ed0594' User entered 'No (N)'	System	31 Aug 2020 00:47:39
	System	31 Aug 2020 00:47:39

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e4da9f15-4a9f-4346-aa09-3c9485ed0594'	System	31 Aug 2020 00:47:39
User entered '30 Aug 2020 19:47'	System	31 Aug 2020 00:47:39

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 4'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9a6fd640-21df-47c9-94fa-2ad805ebcab0' User entered 'Yes (Y)'	System	31 Aug 2020 22:16:36
	System	31 Aug 2020 22:16:36

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9a6fd640-21df-47c9-94fa-2ad805ebcab0' User entered '98.4'	System	31 Aug 2020 22:16:36
	System	31 Aug 2020 22:16:36

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9a6fd640-21df-47c9-94fa-2ad805ebcab0'	System	31 Aug 2020 22:16:36
User entered 'No (N)'	System	31 Aug 2020 22:16:36

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9a6fd640-21df-47c9-94fa-2ad805ebcab0' User entered '31 Aug 2020 17:16'	System	31 Aug 2020 22:16:36
	System	31 Aug 2020 22:16:36

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 5'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'bcc9bb8e-164b-49d4-a74d-be8cd297bccf' User entered 'Yes (Y)'	System	01 Sep 2020 22:58:44
	System	01 Sep 2020 22:58:44

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'bcc9bb8e-164b-49d4-a74d-be8cd297bccf' User entered '98.0'	System	01 Sep 2020 22:58:44
	System	01 Sep 2020 22:58:44

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'bcc9bb8e-164b-49d4-a74d-be8cd297bccf' User entered 'No (N)'	System	01 Sep 2020 22:58:44
	System	01 Sep 2020 22:58:44

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:42', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'bcc9bb8e-164b-49d4-a74d-be8cd297bccf' User entered '01 Sep 2020 17:58'	System	01 Sep 2020 22:58:44
	System	01 Sep 2020 22:58:44

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 6'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'd7ab42b0-a69f-4e97-8286-36c38c5689a0' User entered 'Yes (Y)'	System	02 Sep 2020 21:37:49
	System	02 Sep 2020 21:37:49

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'd7ab42b0-a69f-4e97-8286-36c38c5689a0' User entered '97.9'	System	02 Sep 2020 21:37:49
	System	02 Sep 2020 21:37:49

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'd7ab42b0-a69f-4e97-8286-36c38c5689a0' User entered 'No (N)'	System	02 Sep 2020 21:37:49
	System	02 Sep 2020 21:37:49

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:44', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'd7ab42b0-a69f-4e97-8286-36c38c5689a0' User entered '02 Sep 2020 16:37'	System	02 Sep 2020 21:37:49
	System	02 Sep 2020 21:37:49

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 7'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '88d742d8-ce21-457c-8cd5-3240e291d9a4' User entered 'Yes (Y)'	System	04 Sep 2020 00:57:47
	System	04 Sep 2020 00:57:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '88d742d8-ce21-457c-8cd5-3240e291d9a4' User entered '98.4'	System	04 Sep 2020 00:57:47
	System	04 Sep 2020 00:57:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:40', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '88d742d8-ce21-457c-8cd5-3240e291d9a4' User entered 'No (N)'	System	04 Sep 2020 00:57:47
	System	04 Sep 2020 00:57:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '88d742d8-ce21-457c-8cd5-3240e291d9a4' User entered '03 Sep 2020 19:57'	System	04 Sep 2020 00:57:47
	System	04 Sep 2020 00:57:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e11148ee-502f-4e3b-91f7-c21dfabd4dda' User entered 'None (1)'	System	28 Aug 2020 17:50:41
	System	28 Aug 2020 17:50:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e11148ee-502f-4e3b-91f7-c21dfabd4dda' User entered 'No (N)'	System	28 Aug 2020 17:50:41
	System	28 Aug 2020 17:50:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:21', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e11148ee-502f-4e3b-91f7-c21dfabd4dda' User entered 'No (N)'	System	28 Aug 2020 17:50:41
	System	28 Aug 2020 17:50:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e11148ee-502f-4e3b-91f7-c21dfabd4dda' User entered 'None (1)'	System	28 Aug 2020 17:50:41
	System	28 Aug 2020 17:50:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:34', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e11148ee-502f-4e3b-91f7-c21dfabd4dda' User entered '28 Aug 2020 12:50'	System	28 Aug 2020 17:50:41
	System	28 Aug 2020 17:50:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 12:29'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 14:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e259bd4a-d645-493e-8424-ed73559d7c87'	System	29 Aug 2020 01:32:16
User entered 'None (1)'	System	29 Aug 2020 01:32:16

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:31:58', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e259bd4a-d645-493e-8424-ed73559d7c87'	System	29 Aug 2020 01:32:16
User entered 'No (N)'	System	29 Aug 2020 01:32:16

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e259bd4a-d645-493e-8424-ed73559d7c87'	System	29 Aug 2020 01:32:16
User entered 'No (N)'	System	29 Aug 2020 01:32:16

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e259bd4a-d645-493e-8424-ed73559d7c87'	System	29 Aug 2020 01:32:16
User entered 'None (1)'	System	29 Aug 2020 01:32:16

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e259bd4a-d645-493e-8424-ed73559d7c87'	System	29 Aug 2020 01:32:16
User entered '28 Aug 2020 20:32'	System	29 Aug 2020 01:32:16

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 15:54'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 2'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:28', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '312c04c6-3d16-4889-adac-dab3068fc8d1' User entered 'None (1)'	System	29 Aug 2020 18:25:41
	System	29 Aug 2020 18:25:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '312c04c6-3d16-4889-adac-dab3068fc8d1' User entered 'No (N)'	System	29 Aug 2020 18:25:41
	System	29 Aug 2020 18:25:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '312c04c6-3d16-4889-adac-dab3068fc8d1' User entered 'No (N)'	System	29 Aug 2020 18:25:41
	System	29 Aug 2020 18:25:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:35', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '312c04c6-3d16-4889-adac-dab3068fc8d1' User entered 'None (1)'	System	29 Aug 2020 18:25:41
	System	29 Aug 2020 18:25:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '312c04c6-3d16-4889-adac-dab3068fc8d1' User entered '29 Aug 2020 13:25'	System	29 Aug 2020 18:25:41
	System	29 Aug 2020 18:25:41

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 3'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e111d820-7035-47aa-8acc-8a58ac79424f' User entered 'None (1)'	System	31 Aug 2020 00:48:01
	System	31 Aug 2020 00:48:01

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e111d820-7035-47aa-8acc-8a58ac79424f' User entered 'No (N)'	System	31 Aug 2020 00:48:01
	System	31 Aug 2020 00:48:01

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:51', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e111d820-7035-47aa-8acc-8a58ac79424f' User entered 'No (N)'	System	31 Aug 2020 00:48:01
	System	31 Aug 2020 00:48:01

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e111d820-7035-47aa-8acc-8a58ac79424f' User entered 'None (1)'	System	31 Aug 2020 00:48:01
	System	31 Aug 2020 00:48:01

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:47:58', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e111d820-7035-47aa-8acc-8a58ac79424f' User entered '30 Aug 2020 19:47'	System	31 Aug 2020 00:48:01
	System	31 Aug 2020 00:48:01

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 4'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:39', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1ee09c0e-37ec-4a86-a8d5-53a5fb2201b4' User entered 'None (1)'	System	31 Aug 2020 22:16:53
	System	31 Aug 2020 22:16:53

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1ee09c0e-37ec-4a86-a8d5-53a5fb2201b4' User entered 'No (N)'	System	31 Aug 2020 22:16:53
	System	31 Aug 2020 22:16:53

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:44', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1ee09c0e-37ec-4a86-a8d5-53a5fb2201b4' User entered 'No (N)'	System	31 Aug 2020 22:16:53
	System	31 Aug 2020 22:16:53

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1ee09c0e-37ec-4a86-a8d5-53a5fb2201b4' User entered 'None (1)'	System	31 Aug 2020 22:16:53
	System	31 Aug 2020 22:16:53

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:51', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1ee09c0e-37ec-4a86-a8d5-53a5fb2201b4'	System	31 Aug 2020 22:16:53
User entered '31 Aug 2020 17:16'	System	31 Aug 2020 22:16:53

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 5'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8d234d31-455a-4ded-8e4e-ec2de657693e' User entered 'None (1)'	System	01 Sep 2020 22:59:02
	System	01 Sep 2020 22:59:02

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8d234d31-455a-4ded-8e4e-ec2de657693e' User entered 'No (N)'	System	01 Sep 2020 22:59:02
	System	01 Sep 2020 22:59:02

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:53', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8d234d31-455a-4ded-8e4e-ec2de657693e' User entered 'No (N)'	System	01 Sep 2020 22:59:02
	System	01 Sep 2020 22:59:02

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8d234d31-455a-4ded-8e4e-ec2de657693e' User entered 'None (1)'	System	01 Sep 2020 22:59:02
	System	01 Sep 2020 22:59:02

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:58:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8d234d31-455a-4ded-8e4e-ec2de657693e' User entered '01 Sep 2020 17:58'	System	01 Sep 2020 22:59:02
	System	01 Sep 2020 22:59:02

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 6'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:36:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b6d9d027-98fc-41a3-bd5b-642ebabf14b1' User entered 'None (1)'	System	02 Sep 2020 21:36:58
	System	02 Sep 2020 21:36:58

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:36:40', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b6d9d027-98fc-41a3-bd5b-642ebabf14b1' User entered 'No (N)'	System	02 Sep 2020 21:36:58
	System	02 Sep 2020 21:36:58

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:36:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b6d9d027-98fc-41a3-bd5b-642ebabf14b1' User entered 'No (N)'	System	02 Sep 2020 21:36:58
	System	02 Sep 2020 21:36:58

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:36:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b6d9d027-98fc-41a3-bd5b-642ebabf14b1' User entered 'None (1)'	System	02 Sep 2020 21:36:58
	System	02 Sep 2020 21:36:58

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:36:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b6d9d027-98fc-41a3-bd5b-642ebabf14b1' User entered '02 Sep 2020 16:36'	System	02 Sep 2020 21:36:58
	System	02 Sep 2020 21:36:58

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 7'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1e42f899-1cd0-4d0e-a47d-69151d044215' User entered 'None (1)'	System	04 Sep 2020 00:57:59
	System	04 Sep 2020 00:57:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:49', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1e42f899-1cd0-4d0e-a47d-69151d044215' User entered 'No (N)'	System	04 Sep 2020 00:57:59
	System	04 Sep 2020 00:57:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1e42f899-1cd0-4d0e-a47d-69151d044215' User entered 'No (N)'	System	04 Sep 2020 00:57:59
	System	04 Sep 2020 00:57:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:54', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1e42f899-1cd0-4d0e-a47d-69151d044215' User entered 'None (1)'	System	04 Sep 2020 00:57:59
	System	04 Sep 2020 00:57:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:57:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1e42f899-1cd0-4d0e-a47d-69151d044215' User entered '03 Sep 2020 19:57'	System	04 Sep 2020 00:57:59
	System	04 Sep 2020 00:57:59

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:42', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:45', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:50:57', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'None (0)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:51:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered 'No (N)'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T12:51:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28893880-e8c1-4dc8-8126-68a46bf3f36e' User entered '28 Aug 2020 12:51'	System	28 Aug 2020 17:51:09
	System	28 Aug 2020 17:51:09

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 12:29'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 14:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:19', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:24', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:32', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'None (0)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:35', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered 'No (N)'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-28T20:32:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'eef6ad49-b893-4ccc-bc0b-689b01453dcf' User entered '28 Aug 2020 20:32'	System	29 Aug 2020 01:32:42
	System	29 Aug 2020 01:32:42

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '28 Aug 2020 15:54'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 2'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:44', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'None (0)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered 'No (N)'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-29T13:25:57', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '28c42c08-a652-4c19-9d40-53b7a24d6c53' User entered '29 Aug 2020 13:25'	System	29 Aug 2020 18:25:59
	System	29 Aug 2020 18:25:59

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 3'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'None (0)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered 'No (N)'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-30T19:48:21', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a58510fe-84eb-4ce7-8b67-df7fe06ada91' User entered '30 Aug 2020 19:48'	System	31 Aug 2020 00:48:22
	System	31 Aug 2020 00:48:22

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 4'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:15:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:15:57', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:15:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'None (0)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered 'No (N)'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-08-31T17:16:16', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0c97dc0f-0361-46bb-aec8-4b1d91183b9d' User entered '31 Aug 2020 17:16'	System	31 Aug 2020 22:16:20
	System	31 Aug 2020 22:16:20

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 5'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:08', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'None (0)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered 'No (N)'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-01T17:59:21', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '825323f4-6821-4c14-a5b7-6e92766bc8fc' User entered '01 Sep 2020 17:59'	System	01 Sep 2020 22:59:24
	System	01 Sep 2020 22:59:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 6'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995' User entered 'None (0)'	System	02 Sep 2020 21:37:24
	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:19', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995'	System	02 Sep 2020 21:37:24
User entered 'No (N)'	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-02T16:37:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '22e164e6-1483-44cf-88f9-4a065dd11995'	System	02 Sep 2020 21:37:24
User entered '02 Sep 2020 16:37'	System	02 Sep 2020 21:37:24

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 7'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:01', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'None (0)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered 'No (N)'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-09-03T19:58:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1141e13e-4dd9-4ccf-a007-25c5d19f94c6' User entered '03 Sep 2020 19:58'	System	04 Sep 2020 00:58:19
	System	04 Sep 2020 00:58:19

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:20:47

US3092259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:11:49

US3092259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '07 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:11:49

US3092259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:11:49

US3092259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:11:49

US3092259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 11:47:26

US3092259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	01 Oct 2020 11:47:26

US3092259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:12:19

US3092259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:12:19

US3092259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:12:19

US3092259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:12:19

US3092259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 11:47:36

US3092259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	01 Oct 2020 11:47:36

US3092259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:13:03

US3092259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:13:03

US3092259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:13:03

US3092259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:13:03

US3092259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 11:47:46

US3092259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	01 Oct 2020 11:47:46

US3092259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:04:41

US3092259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:04:41

US3092259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	01 Oct 2020 15:04:41

US3092259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'VISIT2'	System	01 Oct 2020 15:04:41

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Pre-Dose (PREDOSE)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '09:45'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '1 Oct 2020 09:45'	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '98.5' F	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Oral (Oral)'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '87'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'bpm'	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '17'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'breaths/min'	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '123'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '89'	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Post-Dose (POSTDOSE)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 15:36:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	01 Oct 2020 15:23:06
	Catina Adams (b) (4)	01 Oct 2020 15:23:06
	(b) (4)	

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '10:34' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '1 Oct 2020 10:34'	System	01 Oct 2020 15:36:48
User entered empty.	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '98.6' F reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Oral (Oral)' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '90' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'bpm'	System	01 Oct 2020 15:36:48
User entered empty.	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '18' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'breaths/min'	System	01 Oct 2020 15:36:48
User entered empty.	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '138' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	01 Oct 2020 15:36:48
User entered empty.	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '96' reason for change: Data Entry Error	Catina Adams (b) (4)	01 Oct 2020 15:36:48
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	01 Oct 2020 15:36:48
User entered empty.	System	01 Oct 2020 15:23:06

US3092259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:04:26

US3092259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:04:26

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '10:02'	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '1 Oct 2020 10:02'	System	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Left Arm (LEFT ARM)'	Catina Adams (b) (4)	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'ONCE'	System	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 15:03:29

US3092259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:04:15

US3092259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:04:15

US3092259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '09:58'	Catina Adams (b) (4)	01 Oct 2020 15:04:15

US3092259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '1 Oct 2020 09:58'	System	01 Oct 2020 15:04:15

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '09:54'	Catina Adams (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '1 Oct 2020 09:54'	System	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:17:34
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:17:34
User entered '09:54'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered empty.	System	29 Dec 2020 23:17:34
User entered '1 Oct 2020 09:54'	System	01 Oct 2020 15:03:55

US3092259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:23:15

US3092259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	01 Oct 2020 15:23:15

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:25:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b585875c-ce0c-44c2-8f72-34e31c837b41' User entered 'Yes (Y)'	System	01 Oct 2020 15:25:19
	System	01 Oct 2020 15:25:19

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:25:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b585875c-ce0c-44c2-8f72-34e31c837b41' User entered '98.6'	System	01 Oct 2020 15:25:19
	System	01 Oct 2020 15:25:19

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:25:13', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b585875c-ce0c-44c2-8f72-34e31c837b41' User entered 'No (N)'	System	01 Oct 2020 15:25:19
	System	01 Oct 2020 15:25:19

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:25:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'b585875c-ce0c-44c2-8f72-34e31c837b41' User entered '01 Oct 2020 10:25'	System	01 Oct 2020 15:25:19
	System	01 Oct 2020 15:25:19

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 10:22'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 12:52'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:16', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5fcdea23-ba3d-4750-acf9-60673c923afe' User entered 'Yes (Y)'	System	02 Oct 2020 01:05:39
	System	02 Oct 2020 01:05:39

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5fcdea23-ba3d-4750-acf9-60673c923afe' User entered '98.3'	System	02 Oct 2020 01:05:39
	System	02 Oct 2020 01:05:39

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:26', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5fcdea23-ba3d-4750-acf9-60673c923afe' User entered 'No (N)'	System	02 Oct 2020 01:05:39
	System	02 Oct 2020 01:05:39

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:32', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5fcdea23-ba3d-4750-acf9-60673c923afe' User entered '01 Oct 2020 20:05'	System	02 Oct 2020 01:05:39
	System	02 Oct 2020 01:05:39

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 13:47'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 2'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:26', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0781d934-c591-40c0-ad16-9166a12d43eb' User entered 'Yes (Y)'	System	03 Oct 2020 03:28:43
	System	03 Oct 2020 03:28:43

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:31', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0781d934-c591-40c0-ad16-9166a12d43eb' User entered '98.2'	System	03 Oct 2020 03:28:43
	System	03 Oct 2020 03:28:43

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:35', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0781d934-c591-40c0-ad16-9166a12d43eb' User entered 'No (N)'	System	03 Oct 2020 03:28:43
	System	03 Oct 2020 03:28:43

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0781d934-c591-40c0-ad16-9166a12d43eb' User entered '02 Oct 2020 22:28'	System	03 Oct 2020 03:28:43
	System	03 Oct 2020 03:28:43

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 3'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4009b7fa-f8d0-480b-b477-b1f31cdaa3d0' User entered 'Yes (Y)'	System	04 Oct 2020 04:05:53
	System	04 Oct 2020 04:05:53

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4009b7fa-f8d0-480b-b477-b1f31cdaa3d0' User entered '98.6'	System	04 Oct 2020 04:05:53
	System	04 Oct 2020 04:05:53

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4009b7fa-f8d0-480b-b477-b1f31cdaa3d0'	System	04 Oct 2020 04:05:53
User entered 'No (N)'	System	04 Oct 2020 04:05:53

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4009b7fa-f8d0-480b-b477-b1f31cdaa3d0' User entered '03 Oct 2020 23:05'	System	04 Oct 2020 04:05:53
	System	04 Oct 2020 04:05:53

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 4'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9de1e549-41ec-48d0-9011-f321f7feb4ed' User entered 'Yes (Y)'	System	04 Oct 2020 23:40:45
	System	04 Oct 2020 23:40:45

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9de1e549-41ec-48d0-9011-f321f7feb4ed' User entered '98.4'	System	04 Oct 2020 23:40:45
	System	04 Oct 2020 23:40:45

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:40', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9de1e549-41ec-48d0-9011-f321f7feb4ed' User entered 'No (N)'	System	04 Oct 2020 23:40:45
	System	04 Oct 2020 23:40:45

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:44', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9de1e549-41ec-48d0-9011-f321f7feb4ed' User entered '04 Oct 2020 18:40'	System	04 Oct 2020 23:40:45
	System	04 Oct 2020 23:40:45

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 5'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'dd56895f-1772-4177-b18b-7b04696e3b5e' User entered 'Yes (Y)'	System	06 Oct 2020 01:59:16
	System	06 Oct 2020 01:59:16

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:59:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'dd56895f-1772-4177-b18b-7b04696e3b5e' User entered '98.6'	System	06 Oct 2020 01:59:16
	System	06 Oct 2020 01:59:16

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:59:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'dd56895f-1772-4177-b18b-7b04696e3b5e' User entered 'No (N)'	System	06 Oct 2020 01:59:16
	System	06 Oct 2020 01:59:16

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:59:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'dd56895f-1772-4177-b18b-7b04696e3b5e' User entered '05 Oct 2020 20:59'	System	06 Oct 2020 01:59:16
	System	06 Oct 2020 01:59:16

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 6'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:13', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f93595ee-ab00-4742-9d07-82c0cc22f6d9' User entered 'Yes (Y)'	System	06 Oct 2020 22:27:25
	System	06 Oct 2020 22:27:25

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f93595ee-ab00-4742-9d07-82c0cc22f6d9' User entered '98.7'	System	06 Oct 2020 22:27:25
	System	06 Oct 2020 22:27:25

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:20', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f93595ee-ab00-4742-9d07-82c0cc22f6d9' User entered 'No (N)'	System	06 Oct 2020 22:27:25
	System	06 Oct 2020 22:27:25

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f93595ee-ab00-4742-9d07-82c0cc22f6d9' User entered '06 Oct 2020 17:27'	System	06 Oct 2020 22:27:25
	System	06 Oct 2020 22:27:25

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 7'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:53', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1f1a396a-2921-4801-8b24-166e1c87bd5f' User entered 'Yes (Y)'	System	08 Oct 2020 00:44:11
	System	08 Oct 2020 00:44:11

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:44:01', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1f1a396a-2921-4801-8b24-166e1c87bd5f' User entered '98.5'	System	08 Oct 2020 00:44:11
	System	08 Oct 2020 00:44:11

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:44:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1f1a396a-2921-4801-8b24-166e1c87bd5f' User entered 'No (N)'	System	08 Oct 2020 00:44:11
	System	08 Oct 2020 00:44:11

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:44:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1f1a396a-2921-4801-8b24-166e1c87bd5f' User entered '07 Oct 2020 19:44'	System	08 Oct 2020 00:44:11
	System	08 Oct 2020 00:44:11

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0baf171b-41c5-4b94-af59-b1164bdc7ac0' User entered 'None (1)'	System	01 Oct 2020 15:24:58
	System	01 Oct 2020 15:24:58

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0baf171b-41c5-4b94-af59-b1164bdc7ac0' User entered 'No (N)'	System	01 Oct 2020 15:24:58
	System	01 Oct 2020 15:24:58

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:49', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0baf171b-41c5-4b94-af59-b1164bdc7ac0' User entered 'No (N)'	System	01 Oct 2020 15:24:58
	System	01 Oct 2020 15:24:58

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:53', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0baf171b-41c5-4b94-af59-b1164bdc7ac0' User entered 'None (1)'	System	01 Oct 2020 15:24:58
	System	01 Oct 2020 15:24:58

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '0baf171b-41c5-4b94-af59-b1164bdc7ac0' User entered '01 Oct 2020 10:24'	System	01 Oct 2020 15:24:58
	System	01 Oct 2020 15:24:58

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 10:22'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 12:52'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:06:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'fc960c54-e680-4ef5-b394-095fd162cf7c' User entered 'None (1)'	System	02 Oct 2020 01:06:23
	System	02 Oct 2020 01:06:23

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:06:08', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'fc960c54-e680-4ef5-b394-095fd162cf7c' User entered 'No (N)'	System	02 Oct 2020 01:06:23
	System	02 Oct 2020 01:06:23

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:06:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'fc960c54-e680-4ef5-b394-095fd162cf7c' User entered 'No (N)'	System	02 Oct 2020 01:06:23
	System	02 Oct 2020 01:06:23

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:06:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'fc960c54-e680-4ef5-b394-095fd162cf7c' User entered 'None (1)'	System	02 Oct 2020 01:06:23
	System	02 Oct 2020 01:06:23

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:06:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'fc960c54-e680-4ef5-b394-095fd162cf7c' User entered '01 Oct 2020 20:06'	System	02 Oct 2020 01:06:23
	System	02 Oct 2020 01:06:23

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 13:47'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 2'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:42', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '57179dfd-eefa-4fa7-a710-7005b14023ed' User entered 'None (1)'	System	03 Oct 2020 03:28:59
	System	03 Oct 2020 03:28:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:45', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '57179dfd-eefa-4fa7-a710-7005b14023ed' User entered 'No (N)'	System	03 Oct 2020 03:28:59
	System	03 Oct 2020 03:28:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '57179dfd-eefa-4fa7-a710-7005b14023ed' User entered 'No (N)'	System	03 Oct 2020 03:28:59
	System	03 Oct 2020 03:28:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '57179dfd-eefa-4fa7-a710-7005b14023ed' User entered 'None (1)'	System	03 Oct 2020 03:28:59
	System	03 Oct 2020 03:28:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '57179dfd-eefa-4fa7-a710-7005b14023ed' User entered '02 Oct 2020 22:28'	System	03 Oct 2020 03:28:59
	System	03 Oct 2020 03:28:59

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 3'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '44c09dfe-b9ca-4b6c-9260-5acdb5fb2ff5'	System	04 Oct 2020 04:06:15
User entered 'None (1)'	System	04 Oct 2020 04:06:15

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:05:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '44c09dfe-b9ca-4b6c-9260-5acdb5fb2ff5' User entered 'No (N)'	System	04 Oct 2020 04:06:15
	System	04 Oct 2020 04:06:15

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '44c09dfe-b9ca-4b6c-9260-5acdb5fb2ff5'	System	04 Oct 2020 04:06:15
User entered 'No (N)'	System	04 Oct 2020 04:06:15

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '44c09dfe-b9ca-4b6c-9260-5acdb5fb2ff5'	System	04 Oct 2020 04:06:15
User entered 'None (1)'	System	04 Oct 2020 04:06:15

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '44c09dfe-b9ca-4b6c-9260-5acdb5fb2ff5' User entered '03 Oct 2020 23:06'	System	04 Oct 2020 04:06:15
	System	04 Oct 2020 04:06:15

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 4'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:49', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1c6fec4d-81b0-4959-86d1-8080adab8c91' User entered 'None (1)'	System	04 Oct 2020 23:41:06
	System	04 Oct 2020 23:41:06

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1c6fec4d-81b0-4959-86d1-8080adab8c91' User entered 'No (N)'	System	04 Oct 2020 23:41:06
	System	04 Oct 2020 23:41:06

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1c6fec4d-81b0-4959-86d1-8080adab8c91' User entered 'No (N)'	System	04 Oct 2020 23:41:06
	System	04 Oct 2020 23:41:06

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:40:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1c6fec4d-81b0-4959-86d1-8080adab8c91' User entered 'None (1)'	System	04 Oct 2020 23:41:06
	System	04 Oct 2020 23:41:06

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '1c6fec4d-81b0-4959-86d1-8080adab8c91' User entered '04 Oct 2020 18:41'	System	04 Oct 2020 23:41:06
	System	04 Oct 2020 23:41:06

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 5'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:38', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7dc09f72-5860-431c-a1e0-0c07e1f273ce' User entered 'None (1)'	System	06 Oct 2020 01:58:54
	System	06 Oct 2020 01:58:54

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7dc09f72-5860-431c-a1e0-0c07e1f273ce' User entered 'No (N)'	System	06 Oct 2020 01:58:54
	System	06 Oct 2020 01:58:54

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:44', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7dc09f72-5860-431c-a1e0-0c07e1f273ce' User entered 'No (N)'	System	06 Oct 2020 01:58:54
	System	06 Oct 2020 01:58:54

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:46', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7dc09f72-5860-431c-a1e0-0c07e1f273ce' User entered 'None (1)'	System	06 Oct 2020 01:58:54
	System	06 Oct 2020 01:58:54

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:51', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7dc09f72-5860-431c-a1e0-0c07e1f273ce' User entered '05 Oct 2020 20:58'	System	06 Oct 2020 01:58:54
	System	06 Oct 2020 01:58:54

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 6'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:28', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00ed4e35-abf4-4dfa-a755-7dfb8458d71f' User entered 'None (1)'	System	06 Oct 2020 22:27:39
	System	06 Oct 2020 22:27:39

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00ed4e35-abf4-4dfa-a755-7dfb8458d71f' User entered 'No (N)'	System	06 Oct 2020 22:27:39
	System	06 Oct 2020 22:27:39

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00ed4e35-abf4-4dfa-a755-7dfb8458d71f' User entered 'No (N)'	System	06 Oct 2020 22:27:39
	System	06 Oct 2020 22:27:39

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:35', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00ed4e35-abf4-4dfa-a755-7dfb8458d71f' User entered 'None (1)'	System	06 Oct 2020 22:27:39
	System	06 Oct 2020 22:27:39

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '00ed4e35-abf4-4dfa-a755-7dfb8458d71f' User entered '06 Oct 2020 17:27'	System	06 Oct 2020 22:27:39
	System	06 Oct 2020 22:27:39

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 7'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7791eecd-5ba4-4c35-a5f7-2427088f4971' User entered 'None (1)'	System	08 Oct 2020 00:43:38
	System	08 Oct 2020 00:43:38

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:25', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7791eecd-5ba4-4c35-a5f7-2427088f4971' User entered 'No (N)'	System	08 Oct 2020 00:43:38
	System	08 Oct 2020 00:43:38

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7791eecd-5ba4-4c35-a5f7-2427088f4971' User entered 'No (N)'	System	08 Oct 2020 00:43:38
	System	08 Oct 2020 00:43:38

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7791eecd-5ba4-4c35-a5f7-2427088f4971' User entered 'None (1)'	System	08 Oct 2020 00:43:38
	System	08 Oct 2020 00:43:38

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '7791eecd-5ba4-4c35-a5f7-2427088f4971' User entered '07 Oct 2020 19:43'	System	08 Oct 2020 00:43:38
	System	08 Oct 2020 00:43:38

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:19', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'None (0)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered 'No (N)'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T10:24:32', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '20f29075-8bf7-4716-a3c2-25b981fa7988' User entered '01 Oct 2020 10:24'	System	01 Oct 2020 15:24:36
	System	01 Oct 2020 15:24:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 10:22'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 12:52'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:36', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:40', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:42', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:45', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:47', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'None (0)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered 'No (N)'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-01T20:05:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'f6d8e985-b1af-4350-bcd1-bb92cefa022a' User entered '01 Oct 2020 20:05'	System	02 Oct 2020 01:06:04
	System	02 Oct 2020 01:06:04

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '01 Oct 2020 13:47'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 2'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:28:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:08', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'None (0)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered 'No (N)'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-02T22:29:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '51d03358-ecef-461d-9be6-eb00dfbab358' User entered '02 Oct 2020 22:29'	System	03 Oct 2020 03:29:21
	System	03 Oct 2020 03:29:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 3'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:21', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:24', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:26', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:28', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'None (0)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:34', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered 'No (N)'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-03T23:06:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3d02bbca-0adc-441e-a42b-11ac79641db2' User entered '03 Oct 2020 23:06'	System	04 Oct 2020 04:06:40
	System	04 Oct 2020 04:06:40

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 4'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:13', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'None (0)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered 'No (N)'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-04T18:41:24', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '63ed4b31-2367-463f-8b7f-0f513fe3a3ec' User entered '04 Oct 2020 18:41'	System	04 Oct 2020 23:41:26
	System	04 Oct 2020 23:41:26

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 5'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:15', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:16', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:20', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:22', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:24', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'None (0)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:31', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered 'No (N)'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-05T20:58:33', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '04db0e55-624f-4285-88e6-36b90547402c' User entered '05 Oct 2020 20:58'	System	06 Oct 2020 01:58:36
	System	06 Oct 2020 01:58:36

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 6'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:47', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:49', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:52', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:53', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:55', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'None (0)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:26:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered 'No (N)'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-06T17:27:01', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '8818e456-7d80-457c-b228-9536804c207e' User entered '06 Oct 2020 17:27'	System	06 Oct 2020 22:27:06
	System	06 Oct 2020 22:27:06

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
Data entry locked.	System	01 Oct 2020 15:03:29
User entered 'Day 7'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:42:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:42:58', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:02', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered 'None (0)'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2'	System	08 Oct 2020 00:43:21
User entered 'No (N)'	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-10-07T19:43:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33da0fbd-a4b7-454a-a0b4-11cbd1d8daa2' User entered '07 Oct 2020 19:43'	System	08 Oct 2020 00:43:21
	System	08 Oct 2020 00:43:21

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:03:29

US3092259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:05:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:56:19
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:03:29

US3092259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	destiny robinson (b) (4)	08 Oct 2020 16:48:14

US3092259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '8 Oct 2020'	destiny robinson (b) (4)	08 Oct 2020 16:48:14

US3092259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	destiny robinson (b) (4)	08 Oct 2020 17:04:53
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	destiny robinson (b) (4)	08 Oct 2020 16:48:14
	(b) (4)	

US3092259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'VM 10/8/20...returned call 10/8/20'	(b) (4)	
reason for change: Data Entry Error	destiny robinson (b) (4)	08 Oct 2020 17:04:53
User entered 'vm 10/8/20'	(b) (4)	
	destiny robinson (b) (4)	08 Oct 2020 16:48:14
	(b) (4)	

US3092259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	destiny robinson (b) (4)	08 Oct 2020 16:48:19

US3092259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	08 Oct 2020 16:48:19

US3092259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	destiny robinson (b) (4)	15 Oct 2020 17:59:01

US3092259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '15 Oct 2020'	destiny robinson (b) (4)	15 Oct 2020 17:59:01

US3092259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 17:59:01

US3092259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	destiny robinson (b) (4)	15 Oct 2020 17:59:01

US3092259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	destiny robinson (b) (4)	15 Oct 2020 17:59:06

US3092259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	15 Oct 2020 17:59:06

US3092259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:32:42

US3092259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:32:42

US3092259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:32:42

US3092259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:32:42

US3092259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 14:32:47

US3092259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	23 Oct 2020 14:32:47

US3092259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Nov 2020 16:01:43

US3092259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '5 Nov 2020'	Catina Adams (b) (4)	05 Nov 2020 16:01:43

US3092259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	05 Nov 2020 16:01:43

US3092259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'VISIT3'	System	05 Nov 2020 16:01:43

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '5 Nov 2020'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '10:00'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '5 Nov 2020 10:00'	System	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '98.7' F	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Oral (Oral)'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '76'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'bpm'	System	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '14'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'breaths/min'	System	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '117'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '74'	Catina Adams (b) (4)	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'mmHg'	System	05 Nov 2020 16:01:27

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39

US3092259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39

US3092259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Nov 2020 16:00:33

US3092259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '5 Nov 2020'	Catina Adams (b) (4)	05 Nov 2020 16:00:33

US3092259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Nov 2020 16:07:07

US3092259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '5 Nov 2020'	Catina Adams (b) (4)	05 Nov 2020 16:07:07

US3092259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '10:05'	Catina Adams (b) (4)	05 Nov 2020 16:07:07

US3092259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered '5 Nov 2020 10:05'	System	05 Nov 2020 16:07:07

US3092259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	Catina Adams (b) (4)	05 Nov 2020 16:00:21

US3092259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	05 Nov 2020 16:00:21

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 64'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you been exposed to someone with 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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 71'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you been exposed to someone with 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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:05:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:05:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered 'Day 78'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you been exposed to someone with 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 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 17:20:47

US3092259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:13
Data entry locked.	System	28 Aug 2020 17:20:47
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 17:20:47

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-23T14:50:37', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '716af8fb-66a1-45f2-987d-9d32e9ca9f9c' User entered 'No (N)'	System	23 Nov 2020 20:50:50

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-23T14:50:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '716af8fb-66a1-45f2-987d-9d32e9ca9f9c' User entered 'No (N)'	System	23 Nov 2020 20:50:50
	System	23 Nov 2020 20:50:50

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-23T14:50:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '716af8fb-66a1-45f2-987d-9d32e9ca9f9c' User entered '23 Nov 2020 14:50:48'	System	23 Nov 2020 20:50:50
	System	23 Nov 2020 20:50:50

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-29T22:00:34', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '73dce3e3-9345-423c-9149-f0512e618b8a' User entered 'No (N)'	System	30 Nov 2020 04:00:46
	System	30 Nov 2020 04:00:46

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-29T22:00:39', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '73dce3e3-9345-423c-9149-f0512e618b8a' User entered 'No (N)'	System	30 Nov 2020 04:00:46
	System	30 Nov 2020 04:00:46

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-11-29T22:00:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '73dce3e3-9345-423c-9149-f0512e618b8a' User entered '29 Nov 2020 22:00:43'	System	30 Nov 2020 04:00:46
	System	30 Nov 2020 04:00:46

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:15:42', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33'	System	08 Dec 2020 11:16:20
User entered 'Yes (Y)'	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:15:47', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33'	System	08 Dec 2020 11:16:20
User entered 'No (N)'	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:15:50', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33'	System	08 Dec 2020 11:16:20
User entered 'No (N)'	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:15:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33'	System	08 Dec 2020 11:16:20
User entered 'Yes (Y)'	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:16:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33'	System	08 Dec 2020 11:16:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-08T05:16:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9c412b5e-9b0d-4639-836b-f6793880de33' User entered '08 Dec 2020 05:16:11'	System	08 Dec 2020 11:16:20
	System	08 Dec 2020 11:16:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:36:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e'	System	15 Dec 2020 01:39:14
User entered 'Yes (Y)'	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:38:45', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e' User entered 'No (N)'	System	15 Dec 2020 01:39:14
	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:38:49', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e' User entered 'No (N)'	System	15 Dec 2020 01:39:14
	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:38:56', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e'	System	15 Dec 2020 01:39:14
User entered 'Yes (Y)'	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:39:01', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e'	System	15 Dec 2020 01:39:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-14T19:39:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '4faf920f-431c-490e-afd7-7dc4b00d2e9e' User entered '14 Dec 2020 19:39:04'	System	15 Dec 2020 01:39:14
	System	15 Dec 2020 01:39:14

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-20T09:24:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2f3e8f0e-621b-468a-bb2c-70b6c4a129b5' User entered 'No (N)'	System	20 Dec 2020 15:24:29
	System	20 Dec 2020 15:24:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-20T09:24:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2f3e8f0e-621b-468a-bb2c-70b6c4a129b5'	System	20 Dec 2020 15:24:29
User entered 'No (N)'	System	20 Dec 2020 15:24:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-20T09:24:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2f3e8f0e-621b-468a-bb2c-70b6c4a129b5' User entered '20 Dec 2020 09:24:27'	System	20 Dec 2020 15:24:29
	System	20 Dec 2020 15:24:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-27T05:28:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e53d50bf-a235-4924-98a7-e5df7c8f7ddc'	System	27 Dec 2020 11:28:34
User entered 'No (N)'	System	27 Dec 2020 11:28:34

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-27T05:28:26', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e53d50bf-a235-4924-98a7-e5df7c8f7ddc'	System	27 Dec 2020 11:28:34
User entered 'No (N)'	System	27 Dec 2020 11:28:34

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2020-12-27T05:28:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e53d50bf-a235-4924-98a7-e5df7c8f7ddc' User entered '27 Dec 2020 05:28:30'	System	27 Dec 2020 11:28:34
	System	27 Dec 2020 11:28:34

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-03T04:10:43', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'cc49754a-e5a6-4f17-8b4e-5b8453c4cd43'	System	03 Jan 2021 10:11:20
User entered 'No (N)'	System	03 Jan 2021 10:11:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-03T04:10:59', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'cc49754a-e5a6-4f17-8b4e-5b8453c4cd43'	System	03 Jan 2021 10:11:20
User entered 'Yes (Y)'	System	03 Jan 2021 10:11:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-03T04:11:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'cc49754a-e5a6-4f17-8b4e-5b8453c4cd43'	System	03 Jan 2021 10:11:20
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 10:11:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-03T04:11:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'cc49754a-e5a6-4f17-8b4e-5b8453c4cd43' User entered '03 Jan 2021 04:11:09'	System	03 Jan 2021 10:11:20
	System	03 Jan 2021 10:11:20

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-10T04:28:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ed61140b-9a7c-4468-b129-f3b6c9a151a0' User entered 'No (N)'	System	10 Jan 2021 10:28:19
	System	10 Jan 2021 10:28:19

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-10T04:28:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ed61140b-9a7c-4468-b129-f3b6c9a151a0'	System	10 Jan 2021 10:28:19
User entered 'No (N)'	System	10 Jan 2021 10:28:19

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-10T04:28:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ed61140b-9a7c-4468-b129-f3b6c9a151a0' User entered '10 Jan 2021 04:28:17'	System	10 Jan 2021 10:28:19
	System	10 Jan 2021 10:28:19

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-17T07:21:09', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '56667b18-45a7-48e8-8ca6-4dac7d3a9553'	System	17 Jan 2021 13:21:22
User entered 'No (N)'	System	17 Jan 2021 13:21:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-17T07:21:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '56667b18-45a7-48e8-8ca6-4dac7d3a9553'	System	17 Jan 2021 13:21:22
User entered 'No (N)'	System	17 Jan 2021 13:21:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-17T07:21:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '56667b18-45a7-48e8-8ca6-4dac7d3a9553'	System	17 Jan 2021 13:21:22
User entered '17 Jan 2021 07:21:18'	System	17 Jan 2021 13:21:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4' User entered 'Yes (Y)'	System	31 Jan 2021 07:00:05
	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4' User entered 'No (N)'	System	31 Jan 2021 07:00:05
	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4' User entered 'No (N)'	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:23', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4' User entered 'Yes (Y)'	System	31 Jan 2021 07:00:05
	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:27', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4'	System	31 Jan 2021 07:00:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-24T09:47:30', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '87bbdce9-3ac6-45c9-9484-c39a36f28af4' User entered '24 Jan 2021 09:47:30'	System	31 Jan 2021 07:00:05
	System	31 Jan 2021 07:00:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:00:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered 'Yes (Y)'	System	31 Jan 2021 07:02:22
	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:00:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered 'No (N)'	System	31 Jan 2021 07:02:22
	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:00:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered 'Yes (Y)'	System	31 Jan 2021 07:02:22
	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '1'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:41', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '0'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:01:48', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9'	System	31 Jan 2021 07:02:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:02:05', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered 'Yes (Y)'	System	31 Jan 2021 07:02:22
	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:02:08', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9'	System	31 Jan 2021 07:02:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-01-31T01:02:12', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9fcf9b98-a5e3-4a6a-add3-c7abbc46aba9' User entered '31 Jan 2021 01:02:12'	System	31 Jan 2021 07:02:22
	System	31 Jan 2021 07:02:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-07T12:08:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '959e260b-4358-4965-955b-7ec847c00ece' User entered 'No (N)'	System	07 Feb 2021 18:08:18
	System	07 Feb 2021 18:08:18

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-07T12:08:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '959e260b-4358-4965-955b-7ec847c00ece' User entered 'No (N)'	System	07 Feb 2021 18:08:18
	System	07 Feb 2021 18:08:18

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-07T12:08:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '959e260b-4358-4965-955b-7ec847c00ece' User entered '07 Feb 2021 12:08:14'	System	07 Feb 2021 18:08:18
	System	07 Feb 2021 18:08:18

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-17T13:03:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3f0a626f-a1a7-47a7-9359-b7ab2c571dd7' User entered 'No (N)'	System	22 Feb 2021 14:23:06

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-17T13:03:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3f0a626f-a1a7-47a7-9359-b7ab2c571dd7' User entered 'No (N)'	System	22 Feb 2021 14:23:06

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-17T13:03:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3f0a626f-a1a7-47a7-9359-b7ab2c571dd7' User entered '17 Feb 2021 13:03:14'	System	22 Feb 2021 14:23:06
	System	22 Feb 2021 14:23:06

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-22T08:23:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33a1de27-8854-43a0-9a5b-21790dec538c' User entered 'No (N)'	System	22 Feb 2021 14:23:11
	System	22 Feb 2021 14:23:11

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-22T08:23:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33a1de27-8854-43a0-9a5b-21790dec538c' User entered 'No (N)'	System	22 Feb 2021 14:23:11
	System	22 Feb 2021 14:23:11

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-22T08:23:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '33a1de27-8854-43a0-9a5b-21790dec538c' User entered '22 Feb 2021 08:23:06'	System	22 Feb 2021 14:23:11
	System	22 Feb 2021 14:23:11

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-28T15:15:03', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5bce9541-1476-4f4a-a7d0-f738223eab65' User entered 'No (N)'	System	28 Feb 2021 21:15:16
	System	28 Feb 2021 21:15:16

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-28T15:15:06', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5bce9541-1476-4f4a-a7d0-f738223eab65' User entered 'No (N)'	System	28 Feb 2021 21:15:16

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-28T15:15:11', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '5bce9541-1476-4f4a-a7d0-f738223eab65' User entered '28 Feb 2021 15:15:11'	System	28 Feb 2021 21:15:16
	System	28 Feb 2021 21:15:16

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-07T09:31:14', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9e352099-60f1-46c2-8c4f-9dfe894d1ac0'	System	07 Mar 2021 15:31:22
User entered 'No (N)'	System	07 Mar 2021 15:31:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-07T09:31:17', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9e352099-60f1-46c2-8c4f-9dfe894d1ac0'	System	07 Mar 2021 15:31:22
User entered 'No (N)'	System	07 Mar 2021 15:31:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-07T09:31:20', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '9e352099-60f1-46c2-8c4f-9dfe894d1ac0' User entered '07 Mar 2021 09:31:20'	System	07 Mar 2021 15:31:22
	System	07 Mar 2021 15:31:22

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-14T09:02:04', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e17ce693-5445-45c9-9450-dadab93d25e3'	System	14 Mar 2021 14:02:13
User entered 'No (N)'	System	14 Mar 2021 14:02:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-14T09:02:07', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e17ce693-5445-45c9-9450-dadab93d25e3'	System	14 Mar 2021 14:02:13
User entered 'No (N)'	System	14 Mar 2021 14:02:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-14T09:02:10', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'e17ce693-5445-45c9-9450-dadab93d25e3' User entered '14 Mar 2021 09:02:10'	System	14 Mar 2021 14:02:13
	System	14 Mar 2021 14:02:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-21T08:01:29', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '6fe38804-b32b-423a-a98d-91eaa1a09830'	System	28 Mar 2021 14:30:29
User entered 'No (N)'	System	28 Mar 2021 14:30:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-21T08:01:32', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '6fe38804-b32b-423a-a98d-91eaa1a09830'	System	28 Mar 2021 14:30:29
User entered 'No (N)'	System	28 Mar 2021 14:30:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-21T08:01:35', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '6fe38804-b32b-423a-a98d-91eaa1a09830' User entered '21 Mar 2021 08:01:35'	System	28 Mar 2021 14:30:29
	System	28 Mar 2021 14:30:29

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-28T09:30:32-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a2f81b5b-64d4-4c0e-ad42-5fd3b03893c3'	System	28 Mar 2021 14:30:45
User entered 'No (N)'	System	28 Mar 2021 14:30:45

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-28T09:30:37-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a2f81b5b-64d4-4c0e-ad42-5fd3b03893c3'	System	28 Mar 2021 14:30:45
User entered 'No (N)'	System	28 Mar 2021 14:30:45

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-03-28T09:30:41-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'a2f81b5b-64d4-4c0e-ad42-5fd3b03893c3' User entered '28 Mar 2021 09:30:41'	System	28 Mar 2021 14:30:45
	System	28 Mar 2021 14:30:45

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-04T09:30:30-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2ebc5e83-c87b-4ea2-b4df-01d2a01cb1a0'	System	04 Apr 2021 14:30:38
User entered 'No (N)'	System	04 Apr 2021 14:30:38

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-04T09:30:32-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2ebc5e83-c87b-4ea2-b4df-01d2a01cb1a0'	System	04 Apr 2021 14:30:38
User entered 'No (N)'	System	04 Apr 2021 14:30:38

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-04T09:30:35-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '2ebc5e83-c87b-4ea2-b4df-01d2a01cb1a0'	System	04 Apr 2021 14:30:38
User entered '04 Apr 2021 09:30:35'	System	04 Apr 2021 14:30:38

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-11T17:13:53-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ebd1e3b2-018f-4051-a88a-a7f690f67c3b' User entered 'No (N)'	System	11 Apr 2021 22:14:08
	System	11 Apr 2021 22:14:08

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-11T17:13:56-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ebd1e3b2-018f-4051-a88a-a7f690f67c3b' User entered 'No (N)'	System	11 Apr 2021 22:14:08
	System	11 Apr 2021 22:14:08

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-11T17:14:01-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'ebd1e3b2-018f-4051-a88a-a7f690f67c3b' User entered '11 Apr 2021 17:14:01'	System	11 Apr 2021 22:14:08
	System	11 Apr 2021 22:14:08

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-18T06:52:53-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c72aa75e-98f0-4646-80bd-a6562f711c62'	System	18 Apr 2021 11:53:05
User entered 'No (N)'	System	18 Apr 2021 11:53:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-18T06:52:57-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c72aa75e-98f0-4646-80bd-a6562f711c62'	System	18 Apr 2021 11:53:05
User entered 'No (N)'	System	18 Apr 2021 11:53:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-18T06:53:02-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c72aa75e-98f0-4646-80bd-a6562f711c62'	System	18 Apr 2021 11:53:05
User entered '18 Apr 2021 06:53:02'	System	18 Apr 2021 11:53:05

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-25T09:31:53-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '78fc8e3f-e764-46d3-8fa5-df6dd9496dde' User entered 'No (N)'	System	25 Apr 2021 14:32:03
	System	25 Apr 2021 14:32:03

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-25T09:31:57-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '78fc8e3f-e764-46d3-8fa5-df6dd9496dde' User entered 'No (N)'	System	25 Apr 2021 14:32:03
	System	25 Apr 2021 14:32:03

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-04-25T09:32:00-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '78fc8e3f-e764-46d3-8fa5-df6dd9496dde' User entered '25 Apr 2021 09:32:00'	System	25 Apr 2021 14:32:03
	System	25 Apr 2021 14:32:03

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-05-02T10:21:57-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c88d8539-20f7-4d10-b0c3-c96e93146ea8'	System	02 May 2021 15:22:21
User entered 'No (N)'	System	02 May 2021 15:22:21

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Have you been exposed to someone with 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 (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-05-02T10:22:05-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c88d8539-20f7-4d10-b0c3-c96e93146ea8'	System	02 May 2021 15:22:21
User entered 'No (N)'	System	02 May 2021 15:22:21

US3092259

Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-05-02T10:22:16-05:00', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: 'c88d8539-20f7-4d10-b0c3-c96e93146ea8'	System	02 May 2021 15:22:21
User entered '02 May 2021 10:22:16'	System	02 May 2021 15:22:21

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:56:13

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:56:13

US3092259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:05:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:13
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:56:13

US3092259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:03

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 23:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-28T15:15:18', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3118d3bb-c5e5-482b-9624-57ef5d74a140' User entered 'No (N)'	System	28 Feb 2021 21:15:23
	System	28 Feb 2021 21:15:23

US3092259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:05:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:49:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45C6312F-0AAF-4448-9879-C94C970C177C)', Time: '2021-02-28T15:15:21', User OID: 'PatientReportedOutcome (US3092259)', ODM File OID: '3118d3bb-c5e5-482b-9624-57ef5d74a140' User entered '28 Feb 2021 15:15:21'	System	28 Feb 2021 21:15:23
	System	28 Feb 2021 21:15:23

US3092259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:23:36

US3092259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:23:36

US3092259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:23:36

US3092259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:23:36

US3092259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:23:41

US3092259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:33:39
User entered 'I'	System	24 Nov 2020 17:23:41

US3092259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:10:12

US3092259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:10:12

US3092259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:10:12

US3092259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:10:12

US3092259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:10:20

US3092259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User entered 'I'	System	29 Dec 2020 23:10:20

US3092259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:27:52

US3092259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:27:52

US3092259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:20:02
User entered 'Contact Made (CONTACT MADE)'		29 Jan 2021 19:27:52

US3092259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '1st attempt made on 01/27/21	(b) (4)	29 Jan 2021 19:27:52
2nd attempt made on 01/28/21	(b) (4), (b) (6)	
3rd attempt made on 01/29/21'		

US3092259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:28:03

US3092259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User entered 'I'	System	29 Jan 2021 19:28:03

US3092259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:34:28

US3092259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:34:28

US3092259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:34:28

US3092259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:34:28

US3092259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:34:35

US3092259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 18:18:51
User entered 'I'	System	26 Feb 2021 18:34:35

US3092259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:25:05

US3092259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:25:05

US3092259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:25:05

US3092259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 23:25:05

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '08:15'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:15'	System	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '82'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '16'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '111'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '73'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 23:26:06

US3092259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 23:26:22

US3092259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:22

US3092259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:41

US3092259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:41

US3092259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '08:43'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:26:41

US3092259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:43'	System	13 Apr 2021 23:26:41

US3092259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 23:27:15

US3092259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 23:27:15

US3092259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:48

US3092259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '27 Apr 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:48

US3092259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:48

US3092259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:48

US3092259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 16:31:55

US3092259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 16:31:55

US3092259

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:54:44

US3092259

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:54:44

US3092259

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:54:44

US3092259

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

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 15:54:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:20:48

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:20:48

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:40:52
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 08:40:52
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1'	System	06 Jan 2021 15:55:44

US3092259

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

Form: Unblinding

Generated On: 09 Jun 2021 15:05:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1'	System	06 Jan 2021 15:55:44

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '184' cm	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '235' lb	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '31.55074'	System	06 Jan 2021 15:58:13
DataPoint set to visible.	System	06 Jan 2021 15:55:44

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '184' cm	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '235' lb	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '31.55074'	System	06 Jan 2021 15:58:13
DataPoint set to visible.	System	06 Jan 2021 15:55:44

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User accepted default value 'Pre-Dose (PREDOSE)'		06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '13:37'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Jan 2021 13:37'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '92'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'bpm'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'breaths/min'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '126'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '82'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '184' cm	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '235' lb	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:05:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '31.55074'	System	06 Jan 2021 15:58:13
DataPoint set to visible.	System	06 Jan 2021 15:55:44

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User accepted default value 'Post-Dose (POSTDOSE)'		06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '14:17'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Jan 2021 14:17'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '93'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'bpm'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'breaths/min'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '134'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '85'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:13

US3092259

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Jan 2021 15:58:13

US3092259

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:24

US3092259

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:58:24

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mRNA-1273'	System	06 Jan 2021 15:59:20
DataPoint set to visible.	System	06 Jan 2021 15:55:44

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '13:45'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Jan 2021 13:45'	System	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'ONCE'	System	06 Jan 2021 15:59:20

US3092259

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

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 15:59:20

US3092259

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:56

US3092259

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:56

US3092259

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '13:43'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:59:56

US3092259

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Jan 2021 13:43'	System	06 Jan 2021 15:59:56

US3092259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:00:15

US3092259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:00:15

US3092259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '13:41'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:00:15

US3092259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Jan 2021 13:41'	System	06 Jan 2021 16:00:15

US3092259

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

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 16:00:21

US3092259

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

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1'	System	06 Jan 2021 16:00:21

US3092259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 23:51:49

US3092259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 23:51:49

US3092259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 23:51:49

US3092259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 23:51:49

US3092259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 23:51:54

US3092259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'I'	System	12 Jan 2021 23:51:54

US3092259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1'	System	12 Jan 2021 23:51:54
DataPoint set to visible.	System	12 Jan 2021 23:51:54

US3092259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:17:26

US3092259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:17:26

US3092259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:17:26

US3092259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'OLD29'	System	06 Feb 2021 01:17:26

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User accepted default value 'Pre-Dose (PREDOSE)'		06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '09:16'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Feb 2021 09:16'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '90'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'bpm'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '15'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'breaths/min'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '142'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '96'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User accepted default value 'Post-Dose (POSTDOSE)'		06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '10:21'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Feb 2021 10:21'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '92'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'bpm'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'breaths/min'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '148'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '95'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	06 Feb 2021 01:18:56

US3092259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:05

US3092259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:05

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 05Feb2021 is reported for Visit OL-D29 in PPD Central lab: however, Immunogenicity Assessment form is not present. Please review and reconcile. Thanks. ' (Site from DM).		09 Apr 2021 07:09:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 05Feb2021 is reported for Visit OL-D29 in PPD Central lab: however, Immunogenicity Assessment form is not present. Please review and reconcile. Thanks. ' answered with 'Unscheduled visit updated.' (Site from DM).	Catina Adams (b) (4) (b) (4)	07 Apr 2021 20:04:09
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 05Feb2021 is reported for Visit OL-D29 in PPD Central lab: however, Immunogenicity Assessment form is not present. Please review and reconcile. Thanks. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 04:38:38
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mRNA-1273'	System	06 Feb 2021 01:19:24
DataPoint set to visible.	System	12 Jan 2021 23:51:54

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '09:49'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '05 Feb 2021 09:49'	System	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'ONCE'	System	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:05:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'INTRAMUSCULAR'	System	06 Feb 2021 01:19:24

US3092259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Feb 2021 01:19:29

US3092259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'I'	System	06 Feb 2021 01:19:29

US3092259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:10:58

US3092259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 02:55:25
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'CONFIRMED DATA IS CORRECT' (Site from System).	(b) (4), (b) (6)	03 Mar 2021 17:12:12
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	03 Mar 2021 17:10:58
User entered '10 Feb 2021'	(b) (4), (b) (6)	03 Mar 2021 17:10:58

US3092259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:10:58

US3092259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:05:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 17:10:58

US3092259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:09:10

US3092259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:05:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'I'	System	01 Mar 2021 17:09:10

US3092259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:09:32

US3092259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 08:06:10
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'original data is correct' (Site from System).	Vicki Martinez (b) (4) (b) (4)	03 Mar 2021 02:46:24
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	01 Mar 2021 17:09:32
User entered '1 Mar 2021'	Marissa Cervenka (b) (4) (b) (4)	01 Mar 2021 17:09:32

US3092259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:09:32

US3092259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:05:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'OLD57'	System	01 Mar 2021 17:09:32

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '1 Mar 2021'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '10:50'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1 Mar 2021 10:50'	System	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '97.9' F	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '88'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'bpm'	System	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '15'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'breaths/min'	System	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '138'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '88'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered 'mmHg'	System	01 Mar 2021 17:26:29

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26

US3092259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:05:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26

US3092259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:42

US3092259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:05:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '1 Mar 2021'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:42

US3092259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:56

US3092259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '1 Mar 2021'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:56

US3092259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '11:00'	Marissa Cervenka (b) (4)	01 Mar 2021 17:26:56

US3092259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:27:26
User entered '1 Mar 2021 11:00'	System	01 Mar 2021 17:26:56

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:03

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '05 Feb 2021'	Catina Adams (b) (4)	07 Apr 2021 20:03:06

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:03

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '0'	Catina Adams (b) (4)	07 Apr 2021 20:03:06

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:03

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '0'	Catina Adams (b) (4)	07 Apr 2021 20:03:06

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:03

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'I'	Catina Adams (b) (4)	07 Apr 2021 20:03:06

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:05:03

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:17
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '0'	Catina Adams (b) (4)	07 Apr 2021 20:03:06

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:22
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'Yes (Y)'	Catina Adams (b) (4)	07 Apr 2021 20:03:34

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:22
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	07 Apr 2021 20:03:46
User entered '05 Feb 2021' reason for change: Data Entry Error	System	07 Apr 2021 20:03:46
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Catina Adams (b) (4)	07 Apr 2021 20:03:34
User entered '05 Jan 2021'	(b) (4)	07 Apr 2021 20:03:34

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:22
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '09:46'	Catina Adams (b) (4)	07 Apr 2021 20:03:34

US3092259

Folder: Unscheduled 05 Feb 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:32:22
User entered '05 Feb 2021 09:46'	System	07 Apr 2021 20:03:46
User entered '05 Jan 2021 09:46'	System	07 Apr 2021 20:03:34

US3092259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:05:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:33
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).		31 Mar 2021 01:28:18
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject was in the hospital at time of e-diary entry. This is captured under the SAE.' (Site from DM).	Catina Adams (b) (4) (b) (4)	28 Mar 2021 11:45:08
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 04:11:25
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 23:13:33

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:33:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Feb 2021 17:33:53
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:34:49
Data point term sent to Coder	System	01 Feb 2021 20:33:58
Coding entries removed.	Marissa Cervenka (b) (4)	01 Feb 2021 20:33:42
User entered 'HEMATURIA DUE TO KIDNEY STONES' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	01 Feb 2021 20:33:42
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'done' (Site from DM).	Marissa Cervenka (b) (4)	01 Feb 2021 20:32:52
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 07:10:20
User coded data point as SOC: Renal and urinary disorders, HLG: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 23:16:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Dec 2020 23:16:22
Data point term sent to Coder	System	29 Dec 2020 23:15:08
User entered 'hematuria'	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User entered empty.	System	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:35:19
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:33:49
User entered 'No (N)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:32:44
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 07:10:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	01 Feb 2021 20:34:17
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	01 Feb 2021 20:34:17
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	01 Feb 2021 20:32:44
User entered '22 Jan 2021' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	01 Feb 2021 20:32:44
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User entered empty.	System	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:35:52
Query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:34:30
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:31:28
User opened query 'Per CDM: The adverse event started after the first dose, yet 'Not applicable' is selected for Relationship to investigational product. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 11:40:11
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:35:44
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:34:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:31:28
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 12:24:55
User entered 'None (NONE)'	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Marissa Cervenka (b) (4)	01 Feb 2021 20:34:17
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User entered '0'	System	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53
User entered '0'	System	29 Dec 2020 23:14:52

US3092259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:34:53

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 20:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 20:37:31
Data point term sent to Coder	System	01 Feb 2021 20:37:01
User entered 'KIDNEY STONES'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '18 Nov 2020'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User entered empty.	System	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '22 Jan 2021'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User entered empty.	System	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Grade 1/Mild (Grade 1/Mild)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 11:41:29
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'will enter' (Site from DM).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 16:56:32
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 03:05:45
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:37:01

US3092259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User entered '0'	System	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05
User entered '1'	System	01 Feb 2021 20:37:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:08
Reviewed for Safety.		02 Feb 2021 13:33:18
User entered 'USA-US086-2021-mRNA-1273-P301000007'	System	02 Feb 2021 13:33:14
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 13:33:14

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:10
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:58:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:58:31
Data point term sent to Coder	System	01 Feb 2021 20:43:05
User entered 'SEPSIS'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:11
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:13
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:15
User entered 'No (N)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:16
User entered '25 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

US3092259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:17:18
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).		26 Feb 2021 16:50:59
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'have not recieved medical records back from hospital ' (Site from Safety).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 16:58:37
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:45:53
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:34:31
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		09 Feb 2021 15:49:17
User entered empty.	System	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:03
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:07:51
User entered 'No (N)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:07:51
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Feb 2021 18:05:25
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:06
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 18:05:25
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 18:05:25
User entered '2 Feb 2021' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:05:25
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 18:03:15
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:08
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:27
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:29
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:32
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

US3092259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:34
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		02 Feb 2021 11:43:22
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'SUBJECT'S HOSPITALIZATION IS ONGOING.' (Site from System).	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:43:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Feb 2021 20:42:15
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:18:35
User entered '25 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per Partial Discharge records, subject was discharged on 03Feb2021. Please review and update. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:50:55
Query 'Per Partial Discharge records, subject was discharged on 03Feb2021. Please review and update. ' answered with 'DONE' (Site from CRA).	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 23:46:05
User entered '3 Feb 2021' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	12 Apr 2021 23:45:48
User opened query 'Per Partial Discharge records, subject was discharged on 03Feb2021. Please review and update. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:51:38
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:29
DataPoint Verified.	(b) (4)	02 Mar 2021 22:18:37
User entered '2 Feb 2021' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:04:28
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 22:30:41
DataPoint Verified.		04 Mar 2021 22:30:34
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).		26 Feb 2021 11:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:04:28
Query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'have not recieved medical records back from hospital ' (Site from System).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 16:59:03
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	01 Feb 2021 20:42:15
User entered 'Unknown (UNK)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	25 Feb 2021 18:05:02
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		25 Feb 2021 18:05:02
User entered '9' reason for change: Data Entry Error destiny robinson	(b) (4)	25 Feb 2021 18:05:02
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	25 Feb 2021 18:04:28
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'PV Query: As the first dose of mRNA-1273 was given on 05 Jan 2021. Please consider updating the action taken from not applicable to no change if the subject will receive the 2nd dose. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:51:05
Query 'PV Query: As the first dose of mRNA-1273 was given on 05 Jan 2021. Please consider updating the action taken from not applicable to no change if the subject will receive the 2nd dose. ' answered with 'updated per query' (Site from Safety).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 17:04:09
User entered 'None (NONE)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 17:04:01
User opened query 'PV Query: As the first dose of mRNA-1273 was given on 05 Jan 2021. Please consider updating the action taken from not applicable to no change if the subject will receive the 2nd dose. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:47:24
User entered 'Not Applicable (NOT APPLICABLE)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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None

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	27 Mar 2021 18:33:13
User entered '1' reason for change: Data Entry Error	Valentine Ebuh (b) (4)	27 Mar 2021 18:33:13
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 01:43:00
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' answered with 'CONFIRMED AND CORRECTED' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	19 Mar 2021 22:53:24
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Mar 2021 22:53:10
User entered '0' reason for change: Data Entry Error	Vicki Martinez (b) (4)	19 Mar 2021 22:53:10
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 13:14:47
User entered '1' reason for change: Data Entry Error	destiny robinson (b) (4)	25 Feb 2021 18:03:15
User entered '0'	(b) (4) Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming medical records are pending. When available, please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
Query 'PV Query: Thank you for confirming medical records are pending. When available, please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Medical records were requested on three separate occasions and still have not been received. The first attempt was on 08FEB2021. The second attempt was on 01MAR2021 and the third attempt was on 12APR2021. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:25:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:45:20
User opened query 'PV Query: Thank you for confirming medical records are pending. When available, please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		03 Mar 2021 13:35:05
User entered '0' reason for change: Data Entry Error destiny robinson	(b) (4) (b) (4)	25 Feb 2021 18:03:15

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'subject states he was on IV antibiotics while in hospital but was not prescribed anything once he was discharged ' (Site from DM).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:02:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4)	15 Feb 2021 03:06:23
User entered 'I'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered '0'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:51:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'reports recovered 2/2/21' (Site from Safety).	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:03:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	25 Feb 2021 18:03:15
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:48:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Marissa Cervenka (b) (4) (b) (4)	01 Feb 2021 20:42:15

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
	(b) (4)	
User entered empty.	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming medical records are pending. When available, please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:13:17
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		30 Apr 2021 14:13:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
Query 'PV Query: Thank you for confirming medical records are pending. When available, please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Medical records were requested on three separate occasions and still have not been received. The first attempt was on 08FEB2021. The second attempt was on 01MAR2021 and the third attempt was on 12APR2021.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:26:28
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records were requested on three separate occasions and still have not been received. The first attempt was on 08FEB2021. The second attempt was on 01MAR2021 and the third attempt was on 12APR2021.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:25:23

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM: Response noted - however narrative states ' SUBJECT TO OBTAIN A COPY OF MEDICAL RECORDS AND CONMEDS AT DISCHARGE AND WILL PROVIDE A COPY TO THE SITE. HE DOES NOT RECALL THE MEDS HE IS TAKING BUT KNOWS THAT HE IS RECEIVING ANTIBIOTICS.' Please update the relevant eCRF's when the data is available. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 18:01:59
User opened query 'Per CDM: Response noted - however narrative states ' SUBJECT TO OBTAIN A COPY OF MEDICAL RECORDS AND CONMEDS AT DISCHARGE AND WILL PROVIDE A COPY TO THE SITE. HE DOES NOT RECALL THE MEDS HE IS TAKING BUT KNOWS THAT HE IS RECEIVING ANTIBIOTICS.' Please update the relevant eCRF's when the data is available. Thank you' (Site from DM).		19 Mar 2021 18:01:14
User closed query 'Per DM CLR: Narrative = RECEIVING ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		19 Mar 2021 18:01:14
DataPoint Verified.		04 Mar 2021 22:32:36
User opened query 'PV Query: Thank you for confirming medical records are pending. When available, please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		03 Mar 2021 13:35:18
User closed query 'PV Query: Please provide cause underlining cause of sepsis if available.' (Site from Safety).		26 Feb 2021 16:51:44
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		26 Feb 2021 16:51:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 16:51:35
User closed query 'Per DM CLR: Narrative = PROCEDURE TO REMOVE KIDNEY STONES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:44:24
Query 'Per DM CLR: Narrative = RECEIVING ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'states he was not on any medications after the hospital visit ' (Site from DM).	destiny robinson (b) (4)	25 Feb 2021 18:07:34
Query 'PV Query: Please provide cause underlining cause of sepsis if available.' answered with 'subject states the sepsis was caused by kidney stone removal procedure. he will bring in hospital records at his visit on 3/1/21 due to attempts to collect records from hospital and none have been recieved at office' (Site from Safety).	destiny robinson (b) (4)	25 Feb 2021 18:07:13
Query 'Per DM CLR: Narrative = PROCEDURE TO REMOVE KIDNEY STONES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'has been added' (Site from DM).	destiny robinson (b) (4)	25 Feb 2021 17:03:28
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'have not recieved medical records back from hospital ' (Site from Safety).	destiny robinson (b) (4)	25 Feb 2021 17:03:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' answered with 'have not recieved medical records back from hospital ' (Site from Safety).	destiny robinson (b) (4)	25 Feb 2021 17:03:07
User opened query 'Per DM CLR: Narrative = RECEIVING ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 03:06:15
User opened query 'Per DM CLR: Narrative = PROCEDURE TO REMOVE KIDNEY STONES. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		15 Feb 2021 03:06:10
User opened query 'PV Query: Please provide cause underlining cause of sepsis if available.' (Site from Safety).		09 Feb 2021 15:49:49
Query 'PV Query: Please confirm if subject was admitted into ICU when possible. ' canceled (Site from Safety).		09 Feb 2021 15:49:33
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		09 Feb 2021 15:47:58
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). ' (Site from Safety).		09 Feb 2021 15:47:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:46:28
User opened query 'PV Query: Please confirm if subject was admitted into ICU when possible. ' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 15:46:13
User entered 'SUBJECT STATES THAT HE WAS HOSPITALIZED ON 25-JAN-2021 FOLLOWING PROCEDURE TO REMOVE KIDNEY STONES (22-JAN-2021. SUBJECT TO OBTAIN A COPY OF MEDICAL RECORDS AND CONMEDS AT DISCHARGE AND WILL PROVIDE A COPY TO THE SITE. HE DOES NOT RECALL THE MEDS HE IS TAKING BUT KNOWS THAT HE IS RECEIVING ANTIBIOTICS.'	Marissa Cervenka (b) (4)	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 18:04:28
User entered '0'	System	01 Feb 2021 20:42:15

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 01:13:56
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:22:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:22:16
Data point term sent to Coder	System	28 Mar 2021 11:25:55
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'UPDATED to worsening' (Site from DM).	Catina Adams (b) (4) (b) (4)	28 Mar 2021 11:25:33
User entered 'WORSENING OF INCONSISTENT AND ELEVATED BLOOD PRESSURE AND MED CHANGES IN HOSPITAL' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	28 Mar 2021 11:25:19
Data point term sent to Coder	System	28 Mar 2021 11:24:54
User closed query 'CDM Coding, please split the term into separate records, as 'INCONSISTENT AND ELEVATED BLOOD PRESSURE' and 'SEPSIS' reporting each term separately with all relevant information e.g. start and stop dates etc ' (Site from System).	System	28 Mar 2021 11:24:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Adverse event](#)

Audit	User	Time (GMT)
Query 'CDM Coding, please split the term into separate records, as 'INCONSISTENT AND ELEVATED BLOOD PRESSURE' and 'SEPSIS' reporting each term separately with all relevant information e.g. start and stop dates etc	Catina Adams (b) (4)	28 Mar 2021 11:24:21
' answered with 'SEPSIS removed from this entry.' (Site from System).		
Data point term sent to Coder	System	28 Mar 2021 11:23:53
User entered 'INCONSISTENT AND ELEVATED BLOOD PRESSURE AND MED CHANGES IN HOSPITAL' reason for change: Data Entry Error	Catina Adams (b) (4)	28 Mar 2021 11:23:33
User opened query 'CDM Coding, please split the term into separate records, as 'INCONSISTENT AND ELEVATED BLOOD PRESSURE' and 'SEPSIS' reporting each term separately with all relevant information e.g. start and stop dates etc	Coder Import (b) (4)	17 Mar 2021 08:47:40
' (Site from System).		
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HYPERTENSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.	(b) (4), (b) (6)	10 Mar 2021 13:15:18
' (Site from DM).		
Data point term sent to Coder	System	26 Feb 2021 18:51:05
User entered 'Inconsistent and elevated blood pressure due to sepsis and med changes in hospital'	(b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User entered empty.	System	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	26 Feb 2021 18:56:54
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Feb 2021 18:56:54
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Feb 2021 18:50:51
User entered '02 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User entered empty.	System	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	29 Mar 2021 19:02:01
User entered '1' reason for change: Data Entry Error	System	29 Mar 2021 19:02:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	destiny robinson (b) (4)	29 Mar 2021 19:02:01
User entered '0'	(b) (4)	26 Feb 2021 18:50:51
	System	26 Feb 2021 18:50:51
	(b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	26 Feb 2021 18:56:54
Data Entry Error	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'		
		26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:21
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User entered '0'	System	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12
User entered '0'	System	26 Feb 2021 18:50:51

US3092259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:05:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:35:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:33
User closed query 'Per CDM, DM CLR re-query on AE#3: Per narrative subject was receiving antibiotics Site response indicates subject "was not on any medications after the hospital visit". Per protocol any concomitant medications relevant to or for the treatment of a SAE need to be recorded. Please review if the mentioned antibiotics need to be entered on the Con Med page. Review and update as appropriate, else clarify. ' (Site from DM).		31 Mar 2021 01:46:57
Query 'Per CDM, DM CLR re-query on AE#3: Per narrative subject was receiving antibiotics. Site response indicates subject "was not on any medications after the hospital visit". Per protocol any concomitant medications relevant to or for the treatment of a SAE need to be recorded. Please review if the mentioned antibiotics need to be entered on the Con Med page. Review and update as appropriate, else clarify. ' answered with 'Sent third request for medical records for name of IV ABT.' (Site from DM).	Catina Adams (b) (4) (b) (4)	28 Mar 2021 11:40:27
User opened query 'Per CDM, DM CLR re-query on AE#3: Per narrative subject was receiving antibiotics. Site response indicates subject "was not on any medications after the hospital visit". Per protocol any concomitant medications relevant to or for the treatment of a SAE need to be recorded. Please review if the mentioned antibiotics need to be entered on the Con Med page. Review and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:45:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:26:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: DEPO-TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 17:56:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:56:03
Data point term sent to Coder	System	24 Nov 2020 17:30:04
User entered 'depo - testosterone'	(b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'low testosterone'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 11:32:55
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'subject reports that is the amount used' (Site from DM).	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User entered '.7'	(b) (4) destiny robinson (b) (4)	25 Feb 2021 17:04:57
	(b) (4), (b) (6)	08 Jan 2021 18:44:07
		24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered 'every week (QS)' reason for change:	Marissa Cervenka (b) (4)	21 Dec 2020 22:39:38
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User closed query 'Per CDM: Please note that "every week" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 05:41:57
Query 'Per CDM: Please note that "every week" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	21 Dec 2020 22:39:45
User entered empty; reason for change Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	21 Dec 2020 22:39:38
User opened query 'Per CDM: Please note that "every week" is one of the available options for Frequency from the list provided. Kindly update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 15:49:05
User entered 'once weekly'	(b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 22:39:38
User entered empty.	System	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 22:39:38
User entered empty.	System	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	21 Dec 2020 22:39:38
User entered empty.	System	24 Nov 2020 17:29:12

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 17:47:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:47:31
Data point term sent to Coder	System	24 Nov 2020 17:31:04
User entered 'atorvastatin'	(b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '80'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 17:30:13

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: TELMISARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:13
Data point term sent to Coder	System	24 Nov 2020 17:32:07
User entered 'telmisartan'	(b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '80'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 17:31:09

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESEVELAM HYDROCHLORIDE, PRODUCTSYNONYM: WELCHOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:14
Data point term sent to Coder	System	24 Nov 2020 17:33:07
User entered 'welchol'	(b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	10 Mar 2021 11:33:17
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'amount reported by subject' (Site from DM). User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). User entered '3760'	Valentine Ebuh (b) (4) (b) (4) destiny robinson (b) (4) (b) (4) (b) (4), (b) (6)	07 Mar 2021 18:32:49 25 Feb 2021 17:05:32 08 Jan 2021 18:44:53 24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 17:32:07

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
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.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:49:14
Data point term sent to Coder	System	24 Nov 2020 17:33:07
User entered 'multivitamin'	(b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User closed query 'Per DM CLR: Indication reflect Prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:48:43
Query 'Per DM CLR: Indication reflect Prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' answered with 'DONE' (Site from DM).	Marissa Cervenka (b) (4) (b) (4)	21 Dec 2020 22:40:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4) (b) (4)	21 Dec 2020 22:40:12
User opened query 'Per DM CLR: Indication reflect Prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 03:19:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'dietary supplement'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '1'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

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

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:05:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 17:32:55

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:05:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:31:33
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Yes (Y)'	destiny robinson (b) (4)	25 Feb 2021 16:56:39

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:05:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '22 Jan 2021'	(b) (4) destiny robinson (b) (4)	25 Feb 2021 16:57:01

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:05:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'kidney stone removal'	(b) (4) destiny robinson (b) (4) (b) (4)	25 Feb 2021 16:57:01

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:05:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'Adverse Event (AE)'	(b) (4) destiny robinson (b) (4) (b) (4)	25 Feb 2021 16:57:01

US3092259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:05:03

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	25 Feb 2021 16:57:01
	(b) (4)	

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '02/Feb/2021 13:35'	(b) (4) System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'I'		02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered '02/Feb/2021 16:57'	(b) (4) System	02 Feb 2021 16:57:53

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
Reviewed for Safety.		26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:53

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered '26/Feb/2021 16:55'	(b) (4) System	26 Feb 2021 16:55:26

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
Reviewed for Safety.		22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
User entered 'l'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 16:55:26

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
User entered '22/Mar/2021 14:37'	(b) (4) System	22 Mar 2021 18:37:33

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:54:31
User entered 'I'		22 Mar 2021 18:37:33

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
User entered '22/Mar/2021 14:54'	(b) (4) System	22 Mar 2021 18:54:46

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
Reviewed for Safety.		29 Mar 2021 13:26:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
User entered 'l'	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:54:46

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:41:52
User entered '29/Mar/2021 13:26'	(b) (4) System	29 Mar 2021 13:26:24

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:41:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:26:24

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'USA-US086-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Yes (Y)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'No (N)'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Valentine'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Ebuh'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered '2701 S Hampton Road, Suite 250'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'Dallas'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 13:35:01
User entered 'TX'	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
	(b) (4)	
Un-reviewed for Safety.	System	13 Apr 2021 17:44:48
User entered (b) (6)	System	13 Apr 2021 17:44:48
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:44:34
Un-reviewed for Safety.		08 Apr 2021 16:19:03
Signature has been broken.		08 Apr 2021 16:19:03
User entered '75224' reason for change: Data Entry Error		08 Apr 2021 16:19:03
DataPoint Un-verified.		08 Apr 2021 15:48:34
DataPoint Verified.		08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:52:46
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:54:31
Un-reviewed for Safety.	System	22 Mar 2021 18:37:33
Signature has been broken.	System	22 Mar 2021 18:37:33
User entered (b) (6)	System	22 Mar 2021 18:37:33
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:37:12
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:32:49
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Vicki Martinez (b) (4)	27 Feb 2021 22:09:45
	(b) (4)	
Un-reviewed for Safety.	System	26 Feb 2021 16:55:26
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered (b) (6)	System	26 Feb 2021 16:55:26
(non-conformant).		
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 16:55:11
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
Un-reviewed for Safety.	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
User entered '75224' reason for change: Data Entry Error	Robert Miranda (b) (4)	02 Feb 2021 22:50:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:35:01

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User entered (b) (6) (non-conformant).	System	02 Feb 2021 13:33:14

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:30
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:57:37
User entered 'US'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:05:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	13 Apr 2021 17:44:48
User entered '6'	System	29 Mar 2021 13:26:24
User entered '5'	System	22 Mar 2021 18:54:46
User entered '4'	System	22 Mar 2021 18:37:33
Signature has been broken.	System	26 Feb 2021 16:55:26
User entered '3'	System	26 Feb 2021 16:55:26
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 03:45:03
	(b) (4)	
User entered '2'	System	02 Feb 2021 16:57:53
User entered '1'	System	02 Feb 2021 13:35:07

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:05:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered '13/Apr/2021 13:44'	(b) (4) System	13 Apr 2021 17:44:48

US3092259

Folder: SAE USA-US086-2021-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:05:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:04:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:44:48