

US3092238 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3092238

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

[Participant ID](#)

US3092238

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

US3092238

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Date of Informed Consent (<i>dd MMM yyyy</i>)	27 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 04:10:05

Generated On: 09 Jun 2021 15:09:13

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 04:10:06

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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 04:10:05

Generated On: 09 Jun 2021 15:09:13

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
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 04:10:05

Generated On: 09 Jun 2021 15:09:13

Condition	RIGHT LEG PAIN (DUE TO FALL)
Start date (dd MMM yyyy)	UN SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
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 04:10:05

Generated On: 09 Jun 2021 15:09:13

Condition	IUD (WILL REPLACE IN 2021)
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Condition	GASTRIC SLEEVE
Start date (dd MMM yyyy)	28 APR 2020
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)	28 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Condition	ACID REFLUX GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:40 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:40
Height (<i>xxx.x</i>)	164.0 cm
Weight (<i>xxx.x</i>)	157.2 kg
BMI (<i>xxx.x</i>)	58.44735 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 27 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 04:10:06

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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 04:10:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

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

What was the participant's randomization number? 145074

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 04:10:06

Generated On: 09 Jun 2021 15:09:13

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 04:10:06

Generated On: 09 Jun 2021 15:09:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 09:40
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 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 04:10:06

Generated On: 09 Jun 2021 15:09:13

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 AUG 2020
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:03
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 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 04:10:06

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:28 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 10:28

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 04:10:06

Generated On: 09 Jun 2021 15:09:13

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

Collection date (dd MMM yyyy)	27 AUG 2020
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Collection time (00:00-23:59)	10:20 (24 HR)
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Collection date and time (derived)	27 AUG 2020 10:20
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:16	27 AUG 2020 10:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:06

Generated On: 09 Jun 2021 15:09:13

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 15:09:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 27 AUG 2020 11:01

PC Open Date & Time 27 AUG 2020 10:48

PC Close Date & Time 27 AUG 2020 13:18

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 AUG 2020 14:13

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

97.8 °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 12:05

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

97.9 °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

29 AUG 2020 17:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

30 AUG 2020 12:05

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:22

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

98.9 °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 12:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

27 AUG 2020 11:02

PC Open Date & Time

27 AUG 2020 10:48

PC Close Date & Time

27 AUG 2020 13:18

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 AUG 2020 14:13

PC Close Date & Time

28 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:12

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 17:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:05

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:01

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 11:02
PC Open Date & Time	27 AUG 2020 10:48
PC Close Date & Time	27 AUG 2020 13:18

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 AUG 2020 14:13

PC Close Date & Time

28 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 12:13
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

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)

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 17:41
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:06
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

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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US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:19
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:01
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3092238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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)	01 OCT 2020
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 09:40
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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)	11:00 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:00
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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.

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	01 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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) 10:28 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:28

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

US3092238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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)	10:26 (24 HR)
Collection date and time (derived)	1 OCT 2020 10:26

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

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	10:21	1 OCT 2020 10:21
Nasopharyngeal Swab 2	No		

US3092238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 10:49

PC Open Date & Time

01 OCT 2020 10:48

PC Close Date & Time

01 OCT 2020 13:18

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 19:21
PC Open Date & Time	01 OCT 2020 14:13
PC Close Date & Time	02 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

98.8 °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 20:10

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

97.9 °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

03 OCT 2020 13:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 19:41

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

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

98.2 °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

05 OCT 2020 12:10

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

98.8 °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 12:02

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 20:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

01 OCT 2020 10:50

PC Open Date & Time

01 OCT 2020 10:48

PC Close Date & Time

01 OCT 2020 13:18

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 19:21

PC Open Date & Time

01 OCT 2020 14:13

PC Close Date & Time

02 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 20:10

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 13:22

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 19:42

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 12:10

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 12:02

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 20:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:50
PC Open Date & Time	01 OCT 2020 10:48
PC Close Date & Time	01 OCT 2020 13:18

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 19:22
PC Open Date & Time	01 OCT 2020 14:13
PC Close Date & Time	02 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 20:10
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:22
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

101 of 2334

EAB) (1725)

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:42
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

103 of 2334

EAB) (1725)

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:10
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 ☒

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

107 of 2334

EAB) (1725)

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 20:40
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3092238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	13:48 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 13:48
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3092238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

29 OCT 2020 14:25

US3092238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:20

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 05:49:24

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 17:40:48

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 01:07:06

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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	24 NOV 2020 14:29:49
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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	28 NOV 2020 00:01:25
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 16:57:45

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 01:34:40
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

21 DEC 2020 18:20:53

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:00:21

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 16:14:10

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 JAN 2021 09:05:01
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 16:01:25

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:00:39

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 00:16:54
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 01:32:35
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 01:25:38

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 10:10:00

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 13:34:08

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 12:48:31

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 09:50:41

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

20 MAR 2021 00:02:53

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

29 MAR 2021 12:05:05

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

06 APR 2021 05:15:22

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 19:29:13

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 08:32:01

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 APR 2021 01:40:51
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

01 MAY 2021 02:24:34

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 271

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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°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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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="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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐
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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	04 AUG 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 362

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

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

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

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐ 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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐ 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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐ 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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐ 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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐
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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐ 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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 SEP 2022 00:01
Patient Cloud Close Date & Time	21 SEP 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
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Patient Cloud Close Date & Time	28 SEP 2022 23:59
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US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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"/>

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3092238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:09:13

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		09 MAR 2021 12:48:48

US3092238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 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

US3092238

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

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 1ST ATTEMPT MADE ON
02/25/21
If Contact Not Made, please provide Comments 2ND ATTEMPT MADE ON
02/26/21
3RD ATTEMPT MADE ON
03/01/21

US3092238

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	VISIT4

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 16:40:59

Generated On: 09 Jun 2021 15:09:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 10:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3092238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	26 MAR 2021 11:04

US3092238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

26 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

Date of Contact	13 JAN 2021
Time of Contact	11:00
Date and Time of Contact (derived)	13 JAN 2021 11:00
Type of Contact	<div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div>

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	11 JAN 2021
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	True	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	13 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	14 JAN 2021
------	-------------

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

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	15 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	17 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Symptom Day

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Date	18 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

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Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

Date of Visit	13 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	13 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 11:18
Height (xxx.x)	164 cm
Weight (xxx.x)	302.4 lb
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092238

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3092238

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 JAN 2021

US3092238

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

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

Visit date (dd MMM yyyy)	29 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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US3092238

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Date of updated informed consent (<i>dd MMM yyyy</i>)	29 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>)	29 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

US3092238

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Height	164.0 cm
Weight	300.6 lb
BMI (xxx.x)	50.80174

US3092238

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Height	164.0 cm
Weight	300.6 lb
BMI (xxx.x)	50.80174
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)	26 FEB 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 09:15
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Height	164.0 cm
Weight	300.6 lb
BMI (xxx.x)	50.80174
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)	26 FEB 2021
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:29
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

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

Form: Physical Examination

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3092238

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

Form: Pregnancy Test

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 FEB 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3092238

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

Form: Exposure

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

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) 26 FEB 2021

What was the treatment time? (00:00-23:59) 10:57 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 10:57

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

US3092238

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

11:51 (24 HR)

Collection date and time (derived)

29 JAN 2021 11:51

US3092238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 04:10:05

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JAN 2021
Collection time (00:00 - 23:59)	11:49
Collection Date and Time (derived)	29 JAN 2021 11:49

US3092238

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

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:31:42

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	OLD29

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

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)	26 MAR 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 10:25
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

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)	26 MAR 2021
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 11:42
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3092238

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 MAR 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3092238

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

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) 26 MAR 2021

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 26 MAR 2021 11:12

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

US3092238

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Mar 2021 01:06:01

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 01:03:40

Generated On: 09 Jun 2021 15:09:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3092238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 01:03:40

Generated On: 09 Jun 2021 15:09:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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	OLD57

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 APR 2021
Time of assessment (<i>00:00-23:59</i>)	10:05 (24 HR)
Vital Signs Date and Time (derived)	27 APR 2021 10:05
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3092238

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 APR 2021

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

US3092238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 APR 2021
Collection time (<i>00:00-23:59</i>)	10:32 (24 HR)
Collection date and time (derived)	27 APR 2021 10:32

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 14 Apr 2021 01:03:40

Generated On: 09 Jun 2021 15:09:13

Visit Date	26 MAR 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	False
Immunogenicity Assessment	True
Pregnancy Test	False

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 01:03:40

Generated On: 09 Jun 2021 15:09:13

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 MAR 2021
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	26 MAR 2021 11:04

US3092238

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

AEID

Adverse event

HEADACHE

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)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

AEID

Adverse event

SEASONAL
ALLERGIES/SINUSITIS

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)

11 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)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

AEID	USA-US086-2021-MRNA-1273-P30 1000016
Adverse event	ABDOMINAL PAIN
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)	17 APR 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)	21 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	18 APR 2021
Hospital Discharge Date (dd MMM yyyy)	21 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

SUBJECT WAS IN THE
HOSPITAL FROM 4/18/21 TO
4/21/21 FOR ABDOMINAL PAIN
THAT BEGAN 4/17/21. SHE WAS
ADMITTED ON 4/18/21 TO
CHARLTON METHODIST
HOSPITAL ON WHEATLAND
DALLAS, TX. WAITING FOR
MEDICAL RECORDS TO GIVE
MORE DETAILS.

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)	0

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 04:10:04

Generated On: 09 Jun 2021 15:09:13

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

Yes ☒

No ☐

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

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Name of Medication MIRENA

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTIVE

Dose per administration 52

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

Q 5 YEARS

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

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EAB) (1725)

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UTERUS	
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Name of Medication COMPAZINE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES/SINUSITIS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

	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)		11 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication ALLERGIES/SINUSITIS

Dose per administration 25

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

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EAB) (1725)

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3092238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Mar 2021 22:51:42

Generated On: 09 Jun 2021 15:09:13

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3092238

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:09:13

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

US3092238

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:09:13

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 ☐

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

SAEID	USA-US086-2021-MRNA-1273-P301000016
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)	1

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 22:38:17

Generated On: 09 Jun 2021 15:09:13

SAEID	USA-US086-2021-MRNA-1273-P301000016
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)	1
Date of submission (Pre-filled from custom function)	29/APR/2021 12:15
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

US3092238 (Prod: Global Medical Research - M3 Wake Research)

US3092238

Form: Participant Creation

Generated On: 09 Jun 2021 15:09:13

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'US3092238'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:09:43

US3092238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:36:03

US3092238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:09:44

US3092238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Clinic (Clinic)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:03

US3092238

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'SCRN'	System	27 Aug 2020 15:36:03

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: Please complete all the relevant forms. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:48:39
Query 'Per CDM: Please complete all the relevant forms. Thank you.' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	11 Dec 2020 20:00:11
User opened query 'Per CDM: Please complete all the relevant forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:01:25
User entered (b) (6) 1988'	RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:09:45

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '32'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'YEARS'	System	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '32'	System	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 05:48:42
Query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	11 Dec 2020 19:59:54
User opened query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:00:58
User entered 'Female (F)'	Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'I'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:09:13

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:36:34

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Aug 2020'	System	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2020'	System	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Amendment 3 (3)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:45

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:09:44

US3092238

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:09:13

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'I'	System	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:09:13

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:01:53

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 23:03:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 23:03:03
Data point term sent to Coder	System	24 Nov 2020 23:02:45
User entered 'LOW BACK PAIN'	(b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Jan 2015'	System	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2015'	System	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:02:31

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Leg pain - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:57:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:57:24
Data point term sent to Coder	System	24 Nov 2020 23:03:46
User entered 'RIGHT LEG PAIN (DUE TO FALL)'	(b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'UN Sep 2019'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Sep 2019'	System	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2019'	System	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:03:14

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Intrauterine contraception, LLT: Intra-uterine contraceptive device - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 23:19:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 23:19:03
Data point term sent to Coder	System	24 Nov 2020 23:04:47
User entered 'IUD (WILL REPLACE IN 2021)'	(b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Jan 2016'	System	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2016'	System	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:03:48

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Nov 2020 23:06:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 23:06:07
Data point term sent to Coder	System	24 Nov 2020 23:04:47
User entered 'GASTRIC SLEEVE'	(b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '28 Apr 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '28 Apr 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Apr 2020'	System	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2020'	System	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'Apr 2020'	System	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '2020'	System	24 Nov 2020 23:04:22

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 23:11:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:11:21
Data point term sent to Coder	System	24 Nov 2020 23:09:53
User entered 'OBESITY'	(b) (4), (b) (6)	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	(b) (4)	24 Nov 2020 23:11:15
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	24 Nov 2020 23:11:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 23:11:08
User entered '28 Apr 2020'		24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:11:15
User entered '0'		24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:11:08
User entered 'No (N)'		24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:11:08
User entered '28 Apr 2020'		24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:11:08
User entered 'Apr 2020'	System	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:11:08
User entered '2020'	System	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:11:08
User entered 'Apr 2020'	System	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:11:08
User entered '2020'	System	24 Nov 2020 23:09:40

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 23:20:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:20:03
Data point term sent to Coder	System	24 Nov 2020 23:10:53
User entered 'ACID REFLUX GASTROESOPHAGEAL REFLUX DISEASE'	(b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:10:41

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Nov 2020 23:14:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 23:14:41
User entered '09:40' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 23:14:41
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 23:14:27
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '27 Aug 2020 09:40'	System	24 Nov 2020 23:14:41
User entered empty.	System	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '164.0' cm	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27
DataPoint set to visible.	System	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '157.2' kg	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27
DataPoint set to visible.	System	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered '58.44735'	System	24 Nov 2020 23:14:27
DataPoint set to visible.	System	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'kg/m2'	System	24 Nov 2020 23:14:27
DataPoint set to visible.	System	27 Aug 2020 15:36:49

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 05:58:43
Query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	17 Dec 2020 20:52:50
User entered empty; reason for change Data Entry Error	Catina Adams (b) (4) (b) (4)	17 Dec 2020 20:52:35
User opened query 'Per CDM: When the Temperature is recorded as "ND", "Route of measurement" and "If Other, specify" fields should remain empty. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 14:09:05
User entered 'Other (Other)'	(b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'bpm'	System	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'breaths/min'	System	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'mmHg'	System	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered 'mmHg'	System	24 Nov 2020 23:14:27

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41

US3092238

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41

US3092238

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:15:00

US3092238

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:15:00

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:09:13

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:32

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User entered empty.	System	24 Nov 2020 23:31:49

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'I'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:09:13

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:51:41
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:37:26

US3092238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 07:53:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	10 Dec 2020 22:20:54
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:41:01
User entered 'Yes (Y)'	Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:37:52

US3092238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-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)	11 Dec 2020 07:53:25
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-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 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	10 Dec 2020 22:21:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-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 12:56:46
User entered '27 Aug 2020'	Shraddha Dubal (b) (4) (b) (4)	27 Aug 2020 15:37:52

US3092238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Clinic (Clinic)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:37:52

US3092238

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'VISIT1'	System	27 Aug 2020 15:37:52

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:19:27

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '145074'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:19:27

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 15:19:27

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:24

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:38:24

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:38:24

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:24

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:24

US3092238

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:09:13

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 11:01:56
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	11 Dec 2020 19:56:16
User entered 'No (N)'	(b) (4), (b) (6)	11 Dec 2020 03:01:51
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).		24 Nov 2020 22:17:48
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:13:43
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:13:42

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Pre-Dose (PREDOSE)'		24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '09:40'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '27 Aug 2020 09:40'	System	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	24 Nov 2020 23:45:13
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	24 Nov 2020 23:45:13
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 23:45:13
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Nov 2020 23:45:00
User entered '98.2' C	(b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '89'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'bpm'	System	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'breaths/min'	System	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '132'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '75'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	24 Nov 2020 23:45:00

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Post-Dose (POSTDOSE)'		24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11:03'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '27 Aug 2020 11:03'	System	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '65'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'bpm'	System	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'breaths/min'	System	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '125'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '80'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	24 Nov 2020 23:44:07

US3092238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:51

US3092238

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:51

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Dec 2020 06:48:49
Query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' answered with 'Updated' (Site from DM).	Catina Adams (b) (4) (b) (4)	17 Dec 2020 01:15:46
User entered 'No (N)' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	17 Dec 2020 01:15:31
User opened query 'Per CDM: Per CCGs, a Yes or No should be selected for "Was FSH sample collected?". Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 09:43:22
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered empty.	System	24 Nov 2020 23:45:57

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '10:28'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '27 Aug 2020 10:28'	System	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Left Arm (LEFT ARM)'	Shraddha Dubal (b) (4)	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'ONCE'	System	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 15:38:11

US3092238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:46:52

US3092238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:46:52

US3092238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '10:20'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:46:52

US3092238

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '27 Aug 2020 10:20'	System	24 Nov 2020 23:46:52

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '10:16'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '27 Aug 2020 10:16'	System	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered empty.	System	24 Nov 2020 23:47:16

US3092238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) Shraddha Dubal (b) (4)	27 Aug 2020 15:38:31

US3092238

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	27 Aug 2020 15:38:31

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:00:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dedbd790-54a9-4f54-b06e-dd1daf7f75ed' User entered 'Yes (Y)'	System	27 Aug 2020 16:01:51
	System	27 Aug 2020 16:01:51

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:01:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dedbd790-54a9-4f54-b06e-dd1daf7f75ed' User entered '98.1'	System	27 Aug 2020 16:01:51
	System	27 Aug 2020 16:01:51

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:01:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dedbd790-54a9-4f54-b06e-dd1daf7f75ed'	System	27 Aug 2020 16:01:51
User entered 'No (N)'	System	27 Aug 2020 16:01:51

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:01:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dedbd790-54a9-4f54-b06e-dd1daf7f75ed' User entered '27 Aug 2020 11:01'	System	27 Aug 2020 16:01:51
	System	27 Aug 2020 16:01:51

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 10:48'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 14:13'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 2'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:05:25', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'fe3d4b16-7cae-45cd-860f-b24b90ef3324' User entered 'Yes (Y)'	System	28 Aug 2020 17:05:47
	System	28 Aug 2020 17:05:47

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:05:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'fe3d4b16-7cae-45cd-860f-b24b90ef3324' User entered '97.8'	System	28 Aug 2020 17:05:47
	System	28 Aug 2020 17:05:47

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:05:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'fe3d4b16-7cae-45cd-860f-b24b90ef3324'	System	28 Aug 2020 17:05:47
User entered 'No (N)'	System	28 Aug 2020 17:05:47

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:05:42', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'fe3d4b16-7cae-45cd-860f-b24b90ef3324' User entered '28 Aug 2020 12:05'	System	28 Aug 2020 17:05:47
	System	28 Aug 2020 17:05:47

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 3'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:12', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '368ec8c5-f9e8-4e6d-990b-e79865a68ff9' User entered 'Yes (Y)'	System	29 Aug 2020 22:40:27
	System	29 Aug 2020 22:40:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '368ec8c5-f9e8-4e6d-990b-e79865a68ff9' User entered '97.9'	System	29 Aug 2020 22:40:27
	System	29 Aug 2020 22:40:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:24', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '368ec8c5-f9e8-4e6d-990b-e79865a68ff9'	System	29 Aug 2020 22:40:27
User entered 'No (N)'	System	29 Aug 2020 22:40:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '368ec8c5-f9e8-4e6d-990b-e79865a68ff9' User entered '29 Aug 2020 17:40'	System	29 Aug 2020 22:40:27
	System	29 Aug 2020 22:40:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 4'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:27', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '865ab034-3b28-4d96-a609-6bee5a9b1e69'	System	30 Aug 2020 17:05:42
User entered 'Yes (Y)'	System	30 Aug 2020 17:05:42

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '865ab034-3b28-4d96-a609-6bee5a9b1e69' User entered '98.4'	System	30 Aug 2020 17:05:42
	System	30 Aug 2020 17:05:42

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:35', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '865ab034-3b28-4d96-a609-6bee5a9b1e69'	System	30 Aug 2020 17:05:42
User entered 'No (N)'	System	30 Aug 2020 17:05:42

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:38', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '865ab034-3b28-4d96-a609-6bee5a9b1e69'	System	30 Aug 2020 17:05:42
User entered '30 Aug 2020 12:05'	System	30 Aug 2020 17:05:42

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 5'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:22:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f02e7f48-e035-4f4e-bf96-91680804106a' User entered 'Yes (Y)'	System	31 Aug 2020 17:26:20
	System	31 Aug 2020 17:26:20

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:22:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f02e7f48-e035-4f4e-bf96-91680804106a' User entered '98.5'	System	31 Aug 2020 17:26:20
	System	31 Aug 2020 17:26:20

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:22:51', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f02e7f48-e035-4f4e-bf96-91680804106a' User entered 'No (N)'	System	31 Aug 2020 17:26:20
	System	31 Aug 2020 17:26:20

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:22:54', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f02e7f48-e035-4f4e-bf96-91680804106a' User entered '31 Aug 2020 12:22'	System	31 Aug 2020 17:26:20
	System	31 Aug 2020 17:26:20

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 6'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e36b4800-60a8-4556-bbf6-0940dfe15460' User entered 'Yes (Y)'	System	01 Sep 2020 17:18:34
	System	01 Sep 2020 17:18:34

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e36b4800-60a8-4556-bbf6-0940dfe15460' User entered '98.9'	System	01 Sep 2020 17:18:34
	System	01 Sep 2020 17:18:34

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e36b4800-60a8-4556-bbf6-0940dfe15460'	System	01 Sep 2020 17:18:34
User entered 'No (N)'	System	01 Sep 2020 17:18:34

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e36b4800-60a8-4556-bbf6-0940dfe15460' User entered '01 Sep 2020 12:18'	System	01 Sep 2020 17:18:34
	System	01 Sep 2020 17:18:34

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 7'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:00:57', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '02f1df9a-0163-44d2-a207-b705a40f32eb' User entered 'Yes (Y)'	System	02 Sep 2020 17:01:27
	System	02 Sep 2020 17:01:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:03', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '02f1df9a-0163-44d2-a207-b705a40f32eb' User entered '98.9'	System	02 Sep 2020 17:01:27
	System	02 Sep 2020 17:01:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:05', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '02f1df9a-0163-44d2-a207-b705a40f32eb' User entered 'No (N)'	System	02 Sep 2020 17:01:27
	System	02 Sep 2020 17:01:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:07', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '02f1df9a-0163-44d2-a207-b705a40f32eb' User entered '02 Sep 2020 12:01'	System	02 Sep 2020 17:01:27
	System	02 Sep 2020 17:01:27

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:01:52', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b3d080f0-1599-4070-988d-51896792a28b' User entered 'None (1)'	System	27 Aug 2020 16:02:52
	System	27 Aug 2020 16:02:52

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b3d080f0-1599-4070-988d-51896792a28b'	System	27 Aug 2020 16:02:52
User entered 'No (N)'	System	27 Aug 2020 16:02:52

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:09', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b3d080f0-1599-4070-988d-51896792a28b' User entered 'No (N)'	System	27 Aug 2020 16:02:52
	System	27 Aug 2020 16:02:52

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b3d080f0-1599-4070-988d-51896792a28b' User entered 'None (1)'	System	27 Aug 2020 16:02:52
	System	27 Aug 2020 16:02:52

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b3d080f0-1599-4070-988d-51896792a28b' User entered '27 Aug 2020 11:02'	System	27 Aug 2020 16:02:52
	System	27 Aug 2020 16:02:52

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 10:48'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 14:13'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 2'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:12:33', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '5d9543d8-c2d4-487f-b36c-4715cb82a01c' User entered 'None (1)'	System	28 Aug 2020 17:13:05
	System	28 Aug 2020 17:13:05

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:12:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '5d9543d8-c2d4-487f-b36c-4715cb82a01c' User entered 'No (N)'	System	28 Aug 2020 17:13:05
	System	28 Aug 2020 17:13:05

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:12:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '5d9543d8-c2d4-487f-b36c-4715cb82a01c' User entered 'No (N)'	System	28 Aug 2020 17:13:05
	System	28 Aug 2020 17:13:05

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:12:56', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '5d9543d8-c2d4-487f-b36c-4715cb82a01c'	System	28 Aug 2020 17:13:05
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 17:13:05

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:12:59', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '5d9543d8-c2d4-487f-b36c-4715cb82a01c' User entered '28 Aug 2020 12:12'	System	28 Aug 2020 17:13:05
	System	28 Aug 2020 17:13:05

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 3'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:30', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '75213926-1e15-4441-b80c-a1f275814cbf' User entered 'None (1)'	System	29 Aug 2020 22:40:41
	System	29 Aug 2020 22:40:41

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '75213926-1e15-4441-b80c-a1f275814cbf' User entered 'No (N)'	System	29 Aug 2020 22:40:41
	System	29 Aug 2020 22:40:41

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '75213926-1e15-4441-b80c-a1f275814cbf' User entered 'No (N)'	System	29 Aug 2020 22:40:41
	System	29 Aug 2020 22:40:41

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '75213926-1e15-4441-b80c-a1f275814cbf' User entered 'None (1)'	System	29 Aug 2020 22:40:41
	System	29 Aug 2020 22:40:41

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:38', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '75213926-1e15-4441-b80c-a1f275814cbf' User entered '29 Aug 2020 17:40'	System	29 Aug 2020 22:40:41
	System	29 Aug 2020 22:40:41

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 4'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:44', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'da524b04-34dd-4658-b723-d903e83d3326'	System	30 Aug 2020 17:06:01
User entered 'None (1)'	System	30 Aug 2020 17:06:01

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'da524b04-34dd-4658-b723-d903e83d3326'	System	30 Aug 2020 17:06:01
User entered 'No (N)'	System	30 Aug 2020 17:06:01

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'da524b04-34dd-4658-b723-d903e83d3326'	System	30 Aug 2020 17:06:01
User entered 'No (N)'	System	30 Aug 2020 17:06:01

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:56', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'da524b04-34dd-4658-b723-d903e83d3326'	System	30 Aug 2020 17:06:01
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 17:06:01

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:05:59', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'da524b04-34dd-4658-b723-d903e83d3326'	System	30 Aug 2020 17:06:01
User entered '30 Aug 2020 12:05'	System	30 Aug 2020 17:06:01

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 5'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:03', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4f2d3d9a-7d9a-4f48-b8a7-aaf17e56da7a' User entered 'None (1)'	System	31 Aug 2020 17:26:37
	System	31 Aug 2020 17:26:37

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4f2d3d9a-7d9a-4f48-b8a7-aaf17e56da7a' User entered 'No (N)'	System	31 Aug 2020 17:26:37
	System	31 Aug 2020 17:26:37

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4f2d3d9a-7d9a-4f48-b8a7-aaf17e56da7a' User entered 'No (N)'	System	31 Aug 2020 17:26:37
	System	31 Aug 2020 17:26:37

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4f2d3d9a-7d9a-4f48-b8a7-aaf17e56da7a' User entered 'None (1)'	System	31 Aug 2020 17:26:37
	System	31 Aug 2020 17:26:37

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4f2d3d9a-7d9a-4f48-b8a7-aaf17e56da7a' User entered '31 Aug 2020 12:23'	System	31 Aug 2020 17:26:37
	System	31 Aug 2020 17:26:37

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 6'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '47f81fab-f827-4708-8471-f2d58260d812'	System	01 Sep 2020 17:18:51
User entered 'None (1)'	System	01 Sep 2020 17:18:51

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '47f81fab-f827-4708-8471-f2d58260d812' User entered 'No (N)'	System	01 Sep 2020 17:18:51
	System	01 Sep 2020 17:18:51

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:42', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '47f81fab-f827-4708-8471-f2d58260d812' User entered 'No (N)'	System	01 Sep 2020 17:18:51
	System	01 Sep 2020 17:18:51

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '47f81fab-f827-4708-8471-f2d58260d812'	System	01 Sep 2020 17:18:51
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 17:18:51

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '47f81fab-f827-4708-8471-f2d58260d812' User entered '01 Sep 2020 12:18'	System	01 Sep 2020 17:18:51
	System	01 Sep 2020 17:18:51

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 7'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:12', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'df2df911-198b-4978-a957-935e83bc978f' User entered 'None (1)'	System	02 Sep 2020 17:01:50
	System	02 Sep 2020 17:01:50

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'df2df911-198b-4978-a957-935e83bc978f' User entered 'No (N)'	System	02 Sep 2020 17:01:50
	System	02 Sep 2020 17:01:50

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'df2df911-198b-4978-a957-935e83bc978f' User entered 'No (N)'	System	02 Sep 2020 17:01:50
	System	02 Sep 2020 17:01:50

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'df2df911-198b-4978-a957-935e83bc978f' User entered 'None (1)'	System	02 Sep 2020 17:01:50
	System	02 Sep 2020 17:01:50

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'df2df911-198b-4978-a957-935e83bc978f' User entered '02 Sep 2020 12:01'	System	02 Sep 2020 17:01:50
	System	02 Sep 2020 17:01:50

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9'	System	27 Aug 2020 16:03:26
User entered 'None (0)'	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered 'None (0)'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:40', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered 'None (0)'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered 'None (0)'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered 'None (0)'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:50', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered 'None (0)'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9'	System	27 Aug 2020 16:03:26
User entered 'No (N)'	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-27T11:02:58', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'f5dc92d2-0f19-45d2-9e13-f1e4f8a1dfc9' User entered '27 Aug 2020 11:02'	System	27 Aug 2020 16:03:26
	System	27 Aug 2020 16:03:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 10:48'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '27 Aug 2020 14:13'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 2'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:25', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:42', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785' User entered 'None (0)'	System	28 Aug 2020 17:13:53
	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785'	System	28 Aug 2020 17:13:53
User entered 'No (N)'	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-28T12:13:51', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6fd2500e-6ef4-4d09-8a34-9de6b5e0b785'	System	28 Aug 2020 17:13:53
User entered '28 Aug 2020 12:13'	System	28 Aug 2020 17:13:53

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 3'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:44', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48'	System	29 Aug 2020 22:41:03
User entered 'No interference with activity (1)'	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:46', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48' User entered 'None (0)'	System	29 Aug 2020 22:41:03
	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48'	System	29 Aug 2020 22:41:03
User entered 'None (0)'	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:51', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48' User entered 'None (0)'	System	29 Aug 2020 22:41:03
	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:53', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48' User entered 'None (0)'	System	29 Aug 2020 22:41:03
	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48'	System	29 Aug 2020 22:41:03
User entered 'None (0)'	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:40:59', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48'	System	29 Aug 2020 22:41:03
User entered 'No (N)'	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-29T17:41:01', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1e4f2809-efe8-461b-94d1-1cf5eb363b48' User entered '29 Aug 2020 17:41'	System	29 Aug 2020 22:41:03
	System	29 Aug 2020 22:41:03

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 4'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39'	System	30 Aug 2020 17:06:26
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39' User entered 'None (0)'	System	30 Aug 2020 17:06:26
	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39'	System	30 Aug 2020 17:06:26
User entered 'No interference with activity (1)'	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39' User entered 'None (0)'	System	30 Aug 2020 17:06:26
	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39' User entered 'None (0)'	System	30 Aug 2020 17:06:26
	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39' User entered 'None (0)'	System	30 Aug 2020 17:06:26
	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:22', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39'	System	30 Aug 2020 17:06:26
User entered 'No (N)'	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-30T12:06:24', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0f2ef36b-3570-4179-8532-b81e90568d39' User entered '30 Aug 2020 12:06'	System	30 Aug 2020 17:06:26
	System	30 Aug 2020 17:06:26

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 5'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929'	System	31 Aug 2020 17:27:15
User entered 'No interference with activity (1)'	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:23:46', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered 'None (0)'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:24:57', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered 'None (0)'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:25:01', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered 'None (0)'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:25:02', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered 'None (0)'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:25:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered 'None (0)'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:25:11', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929'	System	31 Aug 2020 17:27:15
User entered 'No (N)'	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-08-31T12:25:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dc38b5df-f7df-4b5b-a7ce-91c8309b3929' User entered '31 Aug 2020 12:25'	System	31 Aug 2020 17:27:15
	System	31 Aug 2020 17:27:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 6'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:54', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'No interference with activity (1)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:18:56', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'None (0)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:02', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'None (0)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'None (0)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'None (0)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:08', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'None (0)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:10', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered 'No (N)'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-01T12:19:12', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c987aa16-aeac-483b-9f6e-81529f361c8f' User entered '01 Sep 2020 12:19'	System	01 Sep 2020 17:19:15
	System	01 Sep 2020 17:19:15

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 7'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:35', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:40', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'None (0)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered 'No (N)'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-09-02T12:01:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd9a2a0b0-2fd3-40b2-b66e-1a404f71065e' User entered '02 Sep 2020 12:01'	System	02 Sep 2020 17:02:11
	System	02 Sep 2020 17:02:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 15:38:11

US3092238

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	09 Sep 2020 21:24:56

US3092238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 09:56:26
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Pt was contacted. call completed. ' (Site from System).	destiny robinson (b) (4) (b) (4)	09 Sep 2020 21:25:17
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 21:24:56
User entered '9 Sep 2020'	destiny robinson (b) (4) (b) (4)	09 Sep 2020 21:24:56

US3092238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	09 Sep 2020 21:24:56

US3092238

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	09 Sep 2020 21:24:56

US3092238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	09 Sep 2020 21:25:22

US3092238

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	09 Sep 2020 21:25:22

US3092238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	11 Sep 2020 21:39:41

US3092238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11 Sep 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	11 Sep 2020 21:39:41

US3092238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	11 Sep 2020 21:39:41

US3092238

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	11 Sep 2020 21:39:41

US3092238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	11 Sep 2020 21:39:48

US3092238

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	11 Sep 2020 21:39:48

US3092238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
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	29 Oct 2020 20:07:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 20:07:30
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 17:34:50
User entered empty.	destiny robinson (b) (4)	14 Sep 2020 17:34:50
	(b) (4)	

US3092238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	14 Sep 2020 17:34:50

US3092238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	14 Sep 2020 17:34:50

US3092238

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	14 Sep 2020 17:34:50

US3092238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 11:45:59

US3092238

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	01 Oct 2020 11:45:59

US3092238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:35:15

US3092238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:35:15

US3092238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Clinic (Clinic)'	Catina Adams (b) (4)	01 Oct 2020 15:35:15

US3092238

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'VISIT2'	System	01 Oct 2020 15:35:15

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Pre-Dose (PREDOSE)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Oct 2020 18:37:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 18:37:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Oct 2020 15:58:45
User entered empty.	System	01 Oct 2020 15:58:45
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Oct 2020 18:38:51
User entered '01 Oct 2020' reason for change: Data Entry Error	System	29 Oct 2020 18:38:51
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4)	29 Oct 2020 18:37:59
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '09:40' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '01 Oct 2020 09:40'	System	29 Oct 2020 18:38:51
User entered '27 Aug 2020 09:40'	System	29 Oct 2020 18:37:59
User entered empty.	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '36.6' C reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:40:01
User entered '98.2' F reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '59' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:40:01
User entered '89' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'bpm'	System	29 Oct 2020 18:37:59
User entered empty.	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '15' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:40:01
User entered '18' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'breaths/min'	System	29 Oct 2020 18:37:59
User entered empty.	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '129' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:40:01
User entered '132' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	29 Oct 2020 18:37:59
User entered empty.	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '72' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:40:01
User entered '75' reason for change: Data Entry Error	(b) (4)	
	Marissa Cervenka (b) (4)	29 Oct 2020 18:37:59
User entered empty.	(b) (4)	
	Catina Adams (b) (4)	01 Oct 2020 15:58:45
	(b) (4)	

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	29 Oct 2020 18:37:59
User entered empty.	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Post-Dose (POSTDOSE)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '11:00'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '1 Oct 2020 11:00'	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '98.6' F	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Oral (Oral)'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '62'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'bpm'	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '18'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'breaths/min'	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '147'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '98'	Catina Adams (b) (4)	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	01 Oct 2020 15:58:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:34:55

US3092238

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:34:55

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User closed query 'Per CDM: As per the CCG, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 04:25:01
Query 'Per CDM: As per the CCG, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:42:44
Signature has been broken.	(b) (4), (b) (6)	22 Mar 2021 19:40:09
User entered 'No (N)' reason for change: Data Entry Error		22 Mar 2021 19:40:09
User opened query 'Per CDM: As per the CCG, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly. Thank you.' (Site from DM).		19 Mar 2021 06:44:16
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered empty.	System	11 Dec 2020 03:03:20

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '10:28'	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '1 Oct 2020 10:28'	System	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Left Arm (LEFT ARM)'	Catina Adams (b) (4)	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'ONCE'	System	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 15:34:25

US3092238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:33:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:33:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '10:26'	Catina Adams (b) (4)	01 Oct 2020 15:33:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '1 Oct 2020 10:26'	System	01 Oct 2020 15:33:45

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '1 Oct 2020'	Catina Adams (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '10:21'	Catina Adams (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '1 Oct 2020 10:21'	System	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 00:59:38
User entered 'Yes (Y)'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 00:59:38
User entered '10:21'	Catina Adams (b) (4) (b) (4)	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered empty.	System	30 Dec 2020 00:59:38
User entered '1 Oct 2020 10:21'	System	01 Oct 2020 15:33:01

US3092238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	Catina Adams (b) (4)	01 Oct 2020 15:32:29

US3092238

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	01 Oct 2020 15:32:29

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:30', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'be32b64a-4b64-4eac-8a03-40160c3109cf' User entered 'Yes (Y)'	System	01 Oct 2020 15:49:46
	System	01 Oct 2020 15:49:46

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:35', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'be32b64a-4b64-4eac-8a03-40160c3109cf' User entered '98.6'	System	01 Oct 2020 15:49:46
	System	01 Oct 2020 15:49:46

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'be32b64a-4b64-4eac-8a03-40160c3109cf' User entered 'No (N)'	System	01 Oct 2020 15:49:46
	System	01 Oct 2020 15:49:46

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'be32b64a-4b64-4eac-8a03-40160c3109cf' User entered '01 Oct 2020 10:49'	System	01 Oct 2020 15:49:46
	System	01 Oct 2020 15:49:46

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 10:48'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 13:18'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:20', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd3049f31-ca96-4691-a4e1-fb9e991517b1' User entered 'Yes (Y)'	System	02 Oct 2020 00:21:36
	System	02 Oct 2020 00:21:36

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:27', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd3049f31-ca96-4691-a4e1-fb9e991517b1' User entered '98.3'	System	02 Oct 2020 00:21:36
	System	02 Oct 2020 00:21:36

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:30', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd3049f31-ca96-4691-a4e1-fb9e991517b1' User entered 'No (N)'	System	02 Oct 2020 00:21:36
	System	02 Oct 2020 00:21:36

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd3049f31-ca96-4691-a4e1-fb9e991517b1' User entered '01 Oct 2020 19:21'	System	02 Oct 2020 00:21:36
	System	02 Oct 2020 00:21:36

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 14:13'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 2'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:09:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c00c899-8921-4fb7-b011-a15d5f686da9' User entered 'Yes (Y)'	System	03 Oct 2020 01:10:10
	System	03 Oct 2020 01:10:10

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c00c899-8921-4fb7-b011-a15d5f686da9' User entered '98.8'	System	03 Oct 2020 01:10:10
	System	03 Oct 2020 01:10:10

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c00c899-8921-4fb7-b011-a15d5f686da9' User entered 'No (N)'	System	03 Oct 2020 01:10:10
	System	03 Oct 2020 01:10:10

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c00c899-8921-4fb7-b011-a15d5f686da9' User entered '02 Oct 2020 20:10'	System	03 Oct 2020 01:10:10
	System	03 Oct 2020 01:10:10

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 3'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0991129b-6578-4a06-b27d-941e709c862a' User entered 'Yes (Y)'	System	03 Oct 2020 18:22:22
	System	03 Oct 2020 18:22:22

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:14', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0991129b-6578-4a06-b27d-941e709c862a' User entered '97.9'	System	03 Oct 2020 18:22:22
	System	03 Oct 2020 18:22:22

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0991129b-6578-4a06-b27d-941e709c862a' User entered 'No (N)'	System	03 Oct 2020 18:22:22
	System	03 Oct 2020 18:22:22

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '0991129b-6578-4a06-b27d-941e709c862a' User entered '03 Oct 2020 13:22'	System	03 Oct 2020 18:22:22
	System	03 Oct 2020 18:22:22

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 4'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:41:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bc21f940-a813-4825-a179-0254410135d1' User entered 'Yes (Y)'	System	05 Oct 2020 00:42:00
	System	05 Oct 2020 00:42:00

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:41:50', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bc21f940-a813-4825-a179-0254410135d1' User entered '98.6'	System	05 Oct 2020 00:42:00
	System	05 Oct 2020 00:42:00

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:41:53', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bc21f940-a813-4825-a179-0254410135d1'	System	05 Oct 2020 00:42:00
User entered 'No (N)'	System	05 Oct 2020 00:42:00

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:41:54', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bc21f940-a813-4825-a179-0254410135d1' User entered '04 Oct 2020 19:41'	System	05 Oct 2020 00:42:00
	System	05 Oct 2020 00:42:00

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 5'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:09:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '26ef8465-7d39-41e0-bdb7-e018d331dfe5'	System	05 Oct 2020 17:10:18
User entered 'Yes (Y)'	System	05 Oct 2020 17:10:18

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:10', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '26ef8465-7d39-41e0-bdb7-e018d331dfe5' User entered '98.2'	System	05 Oct 2020 17:10:18
	System	05 Oct 2020 17:10:18

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '26ef8465-7d39-41e0-bdb7-e018d331dfe5'	System	05 Oct 2020 17:10:18
User entered 'No (N)'	System	05 Oct 2020 17:10:18

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '26ef8465-7d39-41e0-bdb7-e018d331dfe5' User entered '05 Oct 2020 12:10'	System	05 Oct 2020 17:10:18
	System	05 Oct 2020 17:10:18

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 6'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:01:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2934b470-8bcc-4ec1-87d9-ef4f78bd480f' User entered 'Yes (Y)'	System	06 Oct 2020 17:02:31
	System	06 Oct 2020 17:02:31

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:01', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2934b470-8bcc-4ec1-87d9-ef4f78bd480f' User entered '98.8'	System	06 Oct 2020 17:02:31
	System	06 Oct 2020 17:02:31

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:03', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2934b470-8bcc-4ec1-87d9-ef4f78bd480f' User entered 'No (N)'	System	06 Oct 2020 17:02:31
	System	06 Oct 2020 17:02:31

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:05', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2934b470-8bcc-4ec1-87d9-ef4f78bd480f' User entered '06 Oct 2020 12:02'	System	06 Oct 2020 17:02:31
	System	06 Oct 2020 17:02:31

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 7'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:03', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c8e8d57-10b2-47a6-93e5-945fc73d9878' User entered 'Yes (Y)'	System	08 Oct 2020 01:40:15
	System	08 Oct 2020 01:40:15

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:08', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c8e8d57-10b2-47a6-93e5-945fc73d9878' User entered '98.5'	System	08 Oct 2020 01:40:15
	System	08 Oct 2020 01:40:15

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:10', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c8e8d57-10b2-47a6-93e5-945fc73d9878' User entered 'No (N)'	System	08 Oct 2020 01:40:15
	System	08 Oct 2020 01:40:15

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:12', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '6c8e8d57-10b2-47a6-93e5-945fc73d9878' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 01:40:15
	System	08 Oct 2020 01:40:15

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:52', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bd773972-09cc-492d-9914-a851622117b0'	System	01 Oct 2020 15:50:25
User entered 'None (1)'	System	01 Oct 2020 15:50:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bd773972-09cc-492d-9914-a851622117b0' User entered 'No (N)'	System	01 Oct 2020 15:50:25
	System	01 Oct 2020 15:50:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:49:57', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bd773972-09cc-492d-9914-a851622117b0' User entered 'No (N)'	System	01 Oct 2020 15:50:25
	System	01 Oct 2020 15:50:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:02', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bd773972-09cc-492d-9914-a851622117b0'	System	01 Oct 2020 15:50:25
User entered 'None (1)'	System	01 Oct 2020 15:50:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bd773972-09cc-492d-9914-a851622117b0' User entered '01 Oct 2020 10:50'	System	01 Oct 2020 15:50:25
	System	01 Oct 2020 15:50:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 10:48'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 13:18'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cfb187d1-4104-4ffe-9f46-703feb6af8c3'	System	02 Oct 2020 00:21:47
User entered 'None (1)'	System	02 Oct 2020 00:21:47

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:38', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cfb187d1-4104-4ffe-9f46-703feb6af8c3'	System	02 Oct 2020 00:21:47
User entered 'No (N)'	System	02 Oct 2020 00:21:47

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cfb187d1-4104-4ffe-9f46-703feb6af8c3'	System	02 Oct 2020 00:21:47
User entered 'No (N)'	System	02 Oct 2020 00:21:47

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cfb187d1-4104-4ffe-9f46-703feb6af8c3'	System	02 Oct 2020 00:21:47
User entered 'None (1)'	System	02 Oct 2020 00:21:47

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cfb187d1-4104-4ffe-9f46-703feb6af8c3' User entered '01 Oct 2020 19:21'	System	02 Oct 2020 00:21:47
	System	02 Oct 2020 00:21:47

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 14:13'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 2'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:10', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c8a38038-54d1-4543-ad27-a6639ffd25fd' User entered 'None (1)'	System	03 Oct 2020 01:10:22
	System	03 Oct 2020 01:10:22

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:12', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c8a38038-54d1-4543-ad27-a6639ffd25fd' User entered 'No (N)'	System	03 Oct 2020 01:10:22
	System	03 Oct 2020 01:10:22

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:14', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c8a38038-54d1-4543-ad27-a6639ffd25fd' User entered 'No (N)'	System	03 Oct 2020 01:10:22
	System	03 Oct 2020 01:10:22

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:16', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c8a38038-54d1-4543-ad27-a6639ffd25fd' User entered 'None (1)'	System	03 Oct 2020 01:10:22
	System	03 Oct 2020 01:10:22

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:18', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c8a38038-54d1-4543-ad27-a6639ffd25fd' User entered '02 Oct 2020 20:10'	System	03 Oct 2020 01:10:22
	System	03 Oct 2020 01:10:22

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 3'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:22', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b1c725b2-d4c2-41e3-952f-a2aadd160c4e' User entered 'None (1)'	System	03 Oct 2020 18:22:35
	System	03 Oct 2020 18:22:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:25', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b1c725b2-d4c2-41e3-952f-a2aadd160c4e' User entered 'No (N)'	System	03 Oct 2020 18:22:35
	System	03 Oct 2020 18:22:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b1c725b2-d4c2-41e3-952f-a2aadd160c4e' User entered 'No (N)'	System	03 Oct 2020 18:22:35
	System	03 Oct 2020 18:22:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b1c725b2-d4c2-41e3-952f-a2aadd160c4e' User entered 'None (1)'	System	03 Oct 2020 18:22:35
	System	03 Oct 2020 18:22:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b1c725b2-d4c2-41e3-952f-a2aadd160c4e' User entered '03 Oct 2020 13:22'	System	03 Oct 2020 18:22:35
	System	03 Oct 2020 18:22:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 4'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:41:59', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c881eb1-bbbd-49b1-8f10-d5723a008d92'	System	05 Oct 2020 00:42:14
User entered 'None (1)'	System	05 Oct 2020 00:42:14

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c881eb1-bbbd-49b1-8f10-d5723a008d92'	System	05 Oct 2020 00:42:14
User entered 'No (N)'	System	05 Oct 2020 00:42:14

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:07', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c881eb1-bbbd-49b1-8f10-d5723a008d92' User entered 'No (N)'	System	05 Oct 2020 00:42:14
	System	05 Oct 2020 00:42:14

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:09', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c881eb1-bbbd-49b1-8f10-d5723a008d92'	System	05 Oct 2020 00:42:14
User entered 'None (1)'	System	05 Oct 2020 00:42:14

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:11', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c881eb1-bbbd-49b1-8f10-d5723a008d92' User entered '04 Oct 2020 19:42'	System	05 Oct 2020 00:42:14
	System	05 Oct 2020 00:42:14

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 5'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3aa357d3-fae9-4e16-888d-3d4cf7727dbc'	System	05 Oct 2020 17:10:36
User entered 'None (1)'	System	05 Oct 2020 17:10:36

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3aa357d3-fae9-4e16-888d-3d4cf7727dbc' User entered 'No (N)'	System	05 Oct 2020 17:10:36
	System	05 Oct 2020 17:10:36

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3aa357d3-fae9-4e16-888d-3d4cf7727dbc' User entered 'No (N)'	System	05 Oct 2020 17:10:36
	System	05 Oct 2020 17:10:36

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:22', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3aa357d3-fae9-4e16-888d-3d4cf7727dbc' User entered 'None (1)'	System	05 Oct 2020 17:10:36
	System	05 Oct 2020 17:10:36

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:24', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3aa357d3-fae9-4e16-888d-3d4cf7727dbc' User entered '05 Oct 2020 12:10'	System	05 Oct 2020 17:10:36
	System	05 Oct 2020 17:10:36

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 6'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:09', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '78f1561e-06c3-432f-af35-077c77e6248e' User entered 'None (1)'	System	06 Oct 2020 17:02:48
	System	06 Oct 2020 17:02:48

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:11', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '78f1561e-06c3-432f-af35-077c77e6248e' User entered 'No (N)'	System	06 Oct 2020 17:02:48
	System	06 Oct 2020 17:02:48

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '78f1561e-06c3-432f-af35-077c77e6248e' User entered 'No (N)'	System	06 Oct 2020 17:02:48
	System	06 Oct 2020 17:02:48

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '78f1561e-06c3-432f-af35-077c77e6248e' User entered 'None (1)'	System	06 Oct 2020 17:02:48
	System	06 Oct 2020 17:02:48

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:16', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '78f1561e-06c3-432f-af35-077c77e6248e' User entered '06 Oct 2020 12:02'	System	06 Oct 2020 17:02:48
	System	06 Oct 2020 17:02:48

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 7'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e1040c9f-fa3c-4e12-a0e9-f56e994f54dd'	System	08 Oct 2020 01:40:35
User entered 'None (1)'	System	08 Oct 2020 01:40:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:17', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e1040c9f-fa3c-4e12-a0e9-f56e994f54dd' User entered 'No (N)'	System	08 Oct 2020 01:40:35
	System	08 Oct 2020 01:40:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e1040c9f-fa3c-4e12-a0e9-f56e994f54dd' User entered 'No (N)'	System	08 Oct 2020 01:40:35
	System	08 Oct 2020 01:40:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e1040c9f-fa3c-4e12-a0e9-f56e994f54dd'	System	08 Oct 2020 01:40:35
User entered 'None (1)'	System	08 Oct 2020 01:40:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e1040c9f-fa3c-4e12-a0e9-f56e994f54dd' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 01:40:35
	System	08 Oct 2020 01:40:35

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:08', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:11', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:14', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:16', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:19', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'None (0)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered 'No (N)'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T10:50:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '575f045a-86ec-4bf8-a5f9-f0193169d46f' User entered '01 Oct 2020 10:50'	System	01 Oct 2020 15:50:41
	System	01 Oct 2020 15:50:41

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 10:48'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 13:18'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:48', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:50', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:51', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:53', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:55', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:21:57', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'None (0)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:22:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered 'No (N)'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-01T19:22:02', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'bbe18657-a495-4f2f-b085-bbca6c90fd0a' User entered '01 Oct 2020 19:22'	System	02 Oct 2020 00:22:09
	System	02 Oct 2020 00:22:09

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '01 Oct 2020 14:13'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 2'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:28', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:46', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'None (0)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:50', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered 'No (N)'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-02T20:10:53', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a2348cc3-4a8d-48ed-912f-afb09098680b' User entered '02 Oct 2020 20:10'	System	03 Oct 2020 01:10:55
	System	03 Oct 2020 01:10:55

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 3'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:35', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:40', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:42', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'None (0)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:48', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered 'No (N)'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-03T13:22:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cbfaa275-110b-4886-a9c9-b97d01ac37d1' User entered '03 Oct 2020 13:22'	System	03 Oct 2020 18:22:51
	System	03 Oct 2020 18:22:51

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 4'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:15', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:16', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:18', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:23', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'None (0)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:28', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered 'No (N)'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-04T19:42:30', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '414a2b49-6fab-467f-a627-af139a7e7566' User entered '04 Oct 2020 19:42'	System	05 Oct 2020 00:42:32
	System	05 Oct 2020 00:42:32

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 5'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:27', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:30', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:33', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'None (0)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:48', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered 'No (N)'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-05T12:10:52', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'e2fe0441-12d3-4a6d-9563-b8c9dce744a9' User entered '05 Oct 2020 12:10'	System	05 Oct 2020 17:10:57
	System	05 Oct 2020 17:10:57

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 6'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:20', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73'	System	06 Oct 2020 17:05:24
User entered 'None (0)'	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:22', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73' User entered 'None (0)'	System	06 Oct 2020 17:05:24
	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:24', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73' User entered 'None (0)'	System	06 Oct 2020 17:05:24
	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:26', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73'	System	06 Oct 2020 17:05:24
User entered 'None (0)'	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:27', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73' User entered 'None (0)'	System	06 Oct 2020 17:05:24
	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:29', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73' User entered 'None (0)'	System	06 Oct 2020 17:05:24
	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73'	System	06 Oct 2020 17:05:24
User entered 'No (N)'	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-06T12:02:33', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '83a7b21f-e047-4586-abbf-7f1c13c8eb73' User entered '06 Oct 2020 12:02'	System	06 Oct 2020 17:05:24
	System	06 Oct 2020 17:05:24

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	01 Oct 2020 15:34:25
User entered 'Day 7'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:38', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'None (0)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

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 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered 'No (N)'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-07T20:40:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ea26f22b-b4a5-4e47-8c3b-f450913ab192' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 01:40:52
	System	08 Oct 2020 01:40:52

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:34:25

US3092238

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:09:13

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:34:25

US3092238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	08 Oct 2020 17:00:05

US3092238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '8 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	08 Oct 2020 17:00:05

US3092238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	08 Oct 2020 17:00:05

US3092238

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	destiny robinson (b) (4)	08 Oct 2020 17:00:05

US3092238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4)	08 Oct 2020 17:00:10

US3092238

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	08 Oct 2020 17:00:10

US3092238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 18:07:55

US3092238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '15 Oct 2020'	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 18:07:55

US3092238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 18:07:55

US3092238

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 18:07:55

US3092238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) destiny robinson (b) (4) (b) (4)	15 Oct 2020 18:07:59

US3092238

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	15 Oct 2020 18:07:59

US3092238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:30:52

US3092238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:30:52

US3092238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:30:52

US3092238

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:30:52

US3092238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:45:29

US3092238

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	29 Oct 2020 19:45:29

US3092238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:58

US3092238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:58

US3092238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:53:58

US3092238

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'VISIT3'	System	29 Oct 2020 19:53:58

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '13:48'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '29 Oct 2020 13:48'	System	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '65'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'bpm'	System	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '16'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'breaths/min'	System	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '125'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '82'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'mmHg'	System	29 Oct 2020 19:54:40

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	03 Apr 2021 23:19:35

US3092238

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35

US3092238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:52

US3092238

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:54:52

US3092238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:57:17

US3092238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:57:17

US3092238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered '14:25'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:57:17

US3092238

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered '29 Oct 2020 14:25'	System	29 Oct 2020 19:57:17

US3092238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 19:57:25

US3092238

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	29 Oct 2020 19:57:25

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 64'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-27T05:49:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '60cb8bd1-0808-4dca-8d9b-2fb6a5e92f9a' User entered 'No (N)'	System	27 Oct 2020 10:49:27
	System	27 Oct 2020 10:49:27

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-27T05:49:20', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '60cb8bd1-0808-4dca-8d9b-2fb6a5e92f9a'	System	27 Oct 2020 10:49:27
User entered 'No (N)'	System	27 Oct 2020 10:49:27

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-10-27T05:49:24', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '60cb8bd1-0808-4dca-8d9b-2fb6a5e92f9a' User entered '27 Oct 2020 05:49:24'	System	27 Oct 2020 10:49:27
	System	27 Oct 2020 10:49:27

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 71'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-03T17:40:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1c549d4f-d463-4859-95af-01b3739b16f1' User entered 'No (N)'	System	03 Nov 2020 23:40:53
	System	03 Nov 2020 23:40:53

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-03T17:40:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1c549d4f-d463-4859-95af-01b3739b16f1'	System	03 Nov 2020 23:40:53
User entered 'No (N)'	System	03 Nov 2020 23:40:53

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-03T17:40:48', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '1c549d4f-d463-4859-95af-01b3739b16f1' User entered '03 Nov 2020 17:40:48'	System	03 Nov 2020 23:40:53
	System	03 Nov 2020 23:40:53

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered 'Day 78'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-10T01:06:59', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3a91166e-2e32-43ec-826b-d6d243b6cfec' User entered 'No (N)'	System	10 Nov 2020 07:07:08
	System	10 Nov 2020 07:07:08

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-10T01:07:02', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3a91166e-2e32-43ec-826b-d6d243b6cfec' User entered 'No (N)'	System	10 Nov 2020 07:07:08
	System	10 Nov 2020 07:07:08

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-10T01:07:06', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3a91166e-2e32-43ec-826b-d6d243b6cfec' User entered '10 Nov 2020 01:07:06'	System	10 Nov 2020 07:07:08
	System	10 Nov 2020 07:07:08

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 15:38:11

US3092238

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:55:14
Data entry locked.	System	27 Aug 2020 15:38:11
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 15:38:11

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-24T14:29:43', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '89393c81-051e-4d6f-82d6-c4044d9045d0' User entered 'No (N)'	System	24 Nov 2020 20:29:53
	System	24 Nov 2020 20:29:53

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-24T14:29:46', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '89393c81-051e-4d6f-82d6-c4044d9045d0'	System	24 Nov 2020 20:29:53
User entered 'No (N)'	System	24 Nov 2020 20:29:53

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-24T14:29:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '89393c81-051e-4d6f-82d6-c4044d9045d0' User entered '24 Nov 2020 14:29:49'	System	24 Nov 2020 20:29:53
	System	24 Nov 2020 20:29:53

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-28T00:01:20', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3b36cbe3-d668-4c6f-a833-2a1e7c25e40b'	System	28 Nov 2020 06:01:54
User entered 'No (N)'	System	28 Nov 2020 06:01:54

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-28T00:01:22', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3b36cbe3-d668-4c6f-a833-2a1e7c25e40b'	System	28 Nov 2020 06:01:54
User entered 'No (N)'	System	28 Nov 2020 06:01:54

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-11-28T00:01:25', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3b36cbe3-d668-4c6f-a833-2a1e7c25e40b' User entered '28 Nov 2020 00:01:25'	System	28 Nov 2020 06:01:54
	System	28 Nov 2020 06:01:54

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-05T16:57:31', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '50ae7302-5f1c-4911-ab6a-17a584289cac'	System	05 Dec 2020 22:57:49
User entered 'No (N)'	System	05 Dec 2020 22:57:49

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-05T16:57:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '50ae7302-5f1c-4911-ab6a-17a584289cac'	System	05 Dec 2020 22:57:49
User entered 'No (N)'	System	05 Dec 2020 22:57:49

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-05T16:57:45', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '50ae7302-5f1c-4911-ab6a-17a584289cac' User entered '05 Dec 2020 16:57:45'	System	05 Dec 2020 22:57:49
	System	05 Dec 2020 22:57:49

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-12T01:34:33', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b0467a51-a161-493f-b1c6-c4bf1096c928'	System	12 Dec 2020 07:34:42
User entered 'No (N)'	System	12 Dec 2020 07:34:42

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-12T01:34:37', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b0467a51-a161-493f-b1c6-c4bf1096c928'	System	12 Dec 2020 07:34:42
User entered 'No (N)'	System	12 Dec 2020 07:34:42

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-12T01:34:40', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'b0467a51-a161-493f-b1c6-c4bf1096c928' User entered '12 Dec 2020 01:34:40'	System	12 Dec 2020 07:34:42
	System	12 Dec 2020 07:34:42

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-21T18:20:47', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dbbf5dea-6d6a-4e9d-8bee-29df99d8d77a' User entered 'No (N)'	System	22 Dec 2020 00:20:55
	System	22 Dec 2020 00:20:55

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-21T18:20:50', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dbbf5dea-6d6a-4e9d-8bee-29df99d8d77a'	System	22 Dec 2020 00:20:55
User entered 'No (N)'	System	22 Dec 2020 00:20:55

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-21T18:20:53', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dbbf5dea-6d6a-4e9d-8bee-29df99d8d77a' User entered '21 Dec 2020 18:20:53'	System	22 Dec 2020 00:20:55
	System	22 Dec 2020 00:20:55

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-28T12:00:14', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '7c2d2b34-de9f-43c1-89ba-4980a5ad39a9' User entered 'No (N)'	System	28 Dec 2020 18:00:30
	System	28 Dec 2020 18:00:30

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-28T12:00:18', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '7c2d2b34-de9f-43c1-89ba-4980a5ad39a9' User entered 'No (N)'	System	28 Dec 2020 18:00:30
	System	28 Dec 2020 18:00:30

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2020-12-28T12:00:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '7c2d2b34-de9f-43c1-89ba-4980a5ad39a9' User entered '28 Dec 2020 12:00:21'	System	28 Dec 2020 18:00:30
	System	28 Dec 2020 18:00:30

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-04T16:14:04', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '80f22121-6513-49a8-b6ed-b50c31ce585e' User entered 'No (N)'	System	04 Jan 2021 22:14:13
	System	04 Jan 2021 22:14:13

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-04T16:14:07', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '80f22121-6513-49a8-b6ed-b50c31ce585e'	System	04 Jan 2021 22:14:13
User entered 'No (N)'	System	04 Jan 2021 22:14:13

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-04T16:14:10', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '80f22121-6513-49a8-b6ed-b50c31ce585e' User entered '04 Jan 2021 16:14:10'	System	04 Jan 2021 22:14:13
	System	04 Jan 2021 22:14:13

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:03:42', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered 'Yes (Y)'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:03:46', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered 'No (N)'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered 'Yes (Y)'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '1'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '0'	System	12 Jan 2021 15:05:15
	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '1'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '1'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '1'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '0'	System	12 Jan 2021 15:05:15
	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '1'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:41', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered '0'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Please 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:52', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:04:58', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62'	System	12 Jan 2021 15:05:15
User entered 'No (N)'	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-12T09:05:01', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '90517e8a-bee8-47be-a962-d93b01417d62' User entered '12 Jan 2021 09:05:01'	System	12 Jan 2021 15:05:15
	System	12 Jan 2021 15:05:15

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-16T16:01:13', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '24882e99-366d-433e-bff7-8269a1b8b170' User entered 'No (N)'	System	16 Jan 2021 22:01:27
	System	16 Jan 2021 22:01:27

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-16T16:01:21', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '24882e99-366d-433e-bff7-8269a1b8b170'	System	16 Jan 2021 22:01:27
User entered 'No (N)'	System	16 Jan 2021 22:01:27

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-16T16:01:25', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '24882e99-366d-433e-bff7-8269a1b8b170' User entered '16 Jan 2021 16:01:25'	System	16 Jan 2021 22:01:27
	System	16 Jan 2021 22:01:27

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-25T12:00:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '8040d372-4a73-470d-9dce-1932fedcb9c9' User entered 'No (N)'	System	25 Jan 2021 18:01:01
	System	25 Jan 2021 18:01:01

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-25T12:00:36', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '8040d372-4a73-470d-9dce-1932fedcb9c9'	System	25 Jan 2021 18:01:01
User entered 'No (N)'	System	25 Jan 2021 18:01:01

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-25T12:00:39', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '8040d372-4a73-470d-9dce-1932fedcb9c9' User entered '25 Jan 2021 12:00:39'	System	25 Jan 2021 18:01:01
	System	25 Jan 2021 18:01:01

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-30T00:16:49', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ee72aac1-4517-4b92-827d-947890ca3d31'	System	30 Jan 2021 06:16:57
User entered 'No (N)'	System	30 Jan 2021 06:16:57

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-30T00:16:51', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ee72aac1-4517-4b92-827d-947890ca3d31'	System	30 Jan 2021 06:16:57
User entered 'No (N)'	System	30 Jan 2021 06:16:57

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-01-30T00:16:54', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ee72aac1-4517-4b92-827d-947890ca3d31' User entered '30 Jan 2021 00:16:54'	System	30 Jan 2021 06:16:57

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-06T01:32:28', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c82cf08-a0db-45fa-a399-8fbe63d324e1' User entered 'No (N)'	System	06 Feb 2021 07:32:38
	System	06 Feb 2021 07:32:38

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-06T01:32:33', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c82cf08-a0db-45fa-a399-8fbe63d324e1' User entered 'No (N)'	System	06 Feb 2021 07:32:38

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-06T01:32:35', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '2c82cf08-a0db-45fa-a399-8fbe63d324e1' User entered '06 Feb 2021 01:32:35'	System	06 Feb 2021 07:32:38
	System	06 Feb 2021 07:32:38

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-13T01:25:32', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '22a424ae-9929-4a2b-819d-9f8e2a603fca' User entered 'No (N)'	System	13 Feb 2021 07:25:41
	System	13 Feb 2021 07:25:41

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-13T01:25:34', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '22a424ae-9929-4a2b-819d-9f8e2a603fca' User entered 'No (N)'	System	13 Feb 2021 07:25:41
	System	13 Feb 2021 07:25:41

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-13T01:25:38', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '22a424ae-9929-4a2b-819d-9f8e2a603fca' User entered '13 Feb 2021 01:25:38'	System	13 Feb 2021 07:25:41
	System	13 Feb 2021 07:25:41

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-22T10:09:56', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c1d4ab16-1f3b-4af7-959e-e853107d93f7'	System	22 Feb 2021 16:10:05
User entered 'No (N)'	System	22 Feb 2021 16:10:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-22T10:09:58', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c1d4ab16-1f3b-4af7-959e-e853107d93f7'	System	22 Feb 2021 16:10:05
User entered 'No (N)'	System	22 Feb 2021 16:10:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-22T10:10:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c1d4ab16-1f3b-4af7-959e-e853107d93f7'	System	22 Feb 2021 16:10:05
User entered '22 Feb 2021 10:10:00'	System	22 Feb 2021 16:10:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-27T07:34:02-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd7d6ac61-eda4-4c81-b3bc-586a4493a36f' User entered 'No (N)'	System	27 Feb 2021 13:34:10
	System	27 Feb 2021 13:34:10

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-27T07:34:05-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd7d6ac61-eda4-4c81-b3bc-586a4493a36f' User entered 'No (N)'	System	27 Feb 2021 13:34:10

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-02-27T07:34:08-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd7d6ac61-eda4-4c81-b3bc-586a4493a36f' User entered '27 Feb 2021 13:34:08'	System	27 Feb 2021 13:34:10
	System	27 Feb 2021 13:34:10

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-09T12:48:25-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c18f2742-0998-44ff-9e38-3c2ced6e0c01'	System	09 Mar 2021 18:48:35
User entered 'No (N)'	System	09 Mar 2021 18:48:35

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-09T12:48:28-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c18f2742-0998-44ff-9e38-3c2ced6e0c01'	System	09 Mar 2021 18:48:35
User entered 'No (N)'	System	09 Mar 2021 18:48:35

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-09T12:48:31-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'c18f2742-0998-44ff-9e38-3c2ced6e0c01'	System	09 Mar 2021 18:48:35
User entered '09 Mar 2021 12:48:31'	System	09 Mar 2021 18:48:35

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-16T09:50:34-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '550b2203-c805-4a90-a21f-f516e2b96072'	System	16 Mar 2021 14:50:44
User entered 'No (N)'	System	16 Mar 2021 14:50:44

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-16T09:50:38-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '550b2203-c805-4a90-a21f-f516e2b96072'	System	16 Mar 2021 14:50:44
User entered 'No (N)'	System	16 Mar 2021 14:50:44

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-16T09:50:41-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '550b2203-c805-4a90-a21f-f516e2b96072' User entered '16 Mar 2021 09:50:41'	System	16 Mar 2021 14:50:44
	System	16 Mar 2021 14:50:44

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-20T00:02:40-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd4bc439c-59fd-413b-912c-7b8456999e48'	System	20 Mar 2021 05:03:28
User entered 'No (N)'	System	20 Mar 2021 05:03:28

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-20T00:02:50-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd4bc439c-59fd-413b-912c-7b8456999e48'	System	20 Mar 2021 05:03:28
User entered 'No (N)'	System	20 Mar 2021 05:03:28

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-20T00:02:53-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'd4bc439c-59fd-413b-912c-7b8456999e48' User entered '20 Mar 2021 00:02:53'	System	20 Mar 2021 05:03:28

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-29T12:05:00-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3ce05d3d-0a40-4c13-8088-47a6ae442f6c' User entered 'No (N)'	System	29 Mar 2021 17:07:31
	System	29 Mar 2021 17:07:31

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-29T12:05:03-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3ce05d3d-0a40-4c13-8088-47a6ae442f6c'	System	29 Mar 2021 17:07:31
User entered 'No (N)'	System	29 Mar 2021 17:07:31

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-29T12:05:05-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '3ce05d3d-0a40-4c13-8088-47a6ae442f6c' User entered '29 Mar 2021 12:05:05'	System	29 Mar 2021 17:07:31
	System	29 Mar 2021 17:07:31

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-06T05:15:16-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'aa3a5e0d-bf3d-4e0c-b7cf-1d8c542f223d'	System	06 Apr 2021 10:15:25
User entered 'No (N)'	System	06 Apr 2021 10:15:25

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-06T05:15:19-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'aa3a5e0d-bf3d-4e0c-b7cf-1d8c542f223d'	System	06 Apr 2021 10:15:25
User entered 'No (N)'	System	06 Apr 2021 10:15:25

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-06T05:15:22-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'aa3a5e0d-bf3d-4e0c-b7cf-1d8c542f223d' User entered '06 Apr 2021 05:15:22'	System	06 Apr 2021 10:15:25
	System	06 Apr 2021 10:15:25

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-14T19:29:08-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a036a441-813c-4690-bd60-16c500995d8b'	System	15 Apr 2021 00:29:19
User entered 'No (N)'	System	15 Apr 2021 00:29:19

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-14T19:29:11-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a036a441-813c-4690-bd60-16c500995d8b'	System	15 Apr 2021 00:29:19
User entered 'No (N)'	System	15 Apr 2021 00:29:19

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-14T19:29:13-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'a036a441-813c-4690-bd60-16c500995d8b'	System	15 Apr 2021 00:29:19
User entered '14 Apr 2021 19:29:13'	System	15 Apr 2021 00:29:19

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-17T08:31:57-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cc0cefb3cdc-4372-b57f-1d01bda46d8c'	System	17 Apr 2021 13:32:05
User entered 'No (N)'	System	17 Apr 2021 13:32:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-17T08:31:59-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cc0cefb3cdc-4372-b57f-1d01bda46d8c'	System	17 Apr 2021 13:32:05
User entered 'No (N)'	System	17 Apr 2021 13:32:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-17T08:32:01-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'cc0cefb3cdc-4372-b57f-1d01bda46d8c'	System	17 Apr 2021 13:32:05
User entered '17 Apr 2021 08:32:01'	System	17 Apr 2021 13:32:05

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:20-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce' User entered 'Yes (Y)'	System	24 Apr 2021 06:41:00
	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:23-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce' User entered 'No (N)'	System	24 Apr 2021 06:41:00
	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:26-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce' User entered 'No (N)'	System	24 Apr 2021 06:41:00
	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:39-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce' User entered 'Yes (Y)'	System	24 Apr 2021 06:41:00
	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Please 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:48-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce'	System	24 Apr 2021 06:41:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-04-24T01:40:51-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: '4e431023-67e5-43e6-aca3-d1e2132255ce' User entered '24 Apr 2021 01:40:51'	System	24 Apr 2021 06:41:00
	System	24 Apr 2021 06:41:00

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-05-01T02:24:30-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dfc700f6-6940-4968-998a-29dc346e4a37'	System	01 May 2021 07:24:39
User entered 'No (N)'	System	01 May 2021 07:24:39

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

Have you been exposed to someone with 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 (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-05-01T02:24:32-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dfc700f6-6940-4968-998a-29dc346e4a37'	System	01 May 2021 07:24:39
User entered 'No (N)'	System	01 May 2021 07:24:39

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-05-01T02:24:34-05:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'dfc700f6-6940-4968-998a-29dc346e4a37'	System	01 May 2021 07:24:39
User entered '01 May 2021 02:24:34'	System	01 May 2021 07:24:39

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 18:55:51

US3092238

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:09:13

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:55:51
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 18:55:51

US3092238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:09:13

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 01:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-09T12:48:43-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ef79cdff-a987-42bb-aa00-71bb18f7f995'	System	09 Mar 2021 18:48:50
User entered 'No (N)'	System	09 Mar 2021 18:48:50

US3092238

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:09:13

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:08:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1DF7DA3-B3DA-44D8-920E-248C61DA6EBA)', Time: '2021-03-09T12:48:48-06:00', User OID: 'PatientReportedOutcome (US3092238)', ODM File OID: 'ef79cdff-a987-42bb-aa00-71bb18f7f995'	System	09 Mar 2021 18:48:50
User entered '09 Mar 2021 12:48:48'	System	09 Mar 2021 18:48:50

US3092238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:14

US3092238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:14

US3092238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:14

US3092238

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:14

US3092238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:55:18

US3092238

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 23:19:35
User entered 'I'	System	24 Nov 2020 22:55:18

US3092238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:35:48

US3092238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:35:48

US3092238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:35:48

US3092238

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:35:48

US3092238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 20:35:52

US3092238

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'I'	System	28 Dec 2020 20:35:52

US3092238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 00:20:26

US3092238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:18:16
User entered '27 Jan 2021'		29 Jan 2021 00:20:26

US3092238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 00:20:26

US3092238

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '1ST ATTEMPT MADE ON 01/27/21 2ND ATTEMPT MADE ON 01/28/21'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 00:20:26

US3092238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 00:20:44

US3092238

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'I'	System	29 Jan 2021 00:20:44

US3092238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:32:52

US3092238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:32:52

US3092238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:32:52

US3092238

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '1st attempt made on 02/25/21 2nd attempt made on 02/26/21 3rd attempt made on 03/01/21'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:32:52

US3092238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 00:33:07

US3092238

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'I'	System	02 Mar 2021 00:33:07

US3092238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:31:46

US3092238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:31:46

US3092238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:31:46

US3092238

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'VISIT4'	System	26 Mar 2021 21:31:46

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered 'Yes (Y)'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '26 Mar 2021'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '10:25'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered '26 Mar 2021 10:25'	System	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '98.2' F	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered 'Oral (Oral)'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered empty.	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '61'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'bpm'	System	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '18'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'breaths/min'	System	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '124'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'mmHg'	System	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
User entered '79'	Catina Adams (b) (4)	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'mmHg'	System	30 Mar 2021 21:11:33

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55

US3092238

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55

US3092238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:31:58

US3092238

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:31:58

US3092238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:06
User entered 'No (N)'		26 Mar 2021 21:32:07

US3092238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:06
User entered empty.		26 Mar 2021 21:32:07

US3092238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '11:04' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:06
User entered empty.		26 Mar 2021 21:32:07

US3092238

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered '26 Mar 2021 11:04'	System	26 Mar 2021 21:33:06
User entered empty.	System	26 Mar 2021 21:32:07

US3092238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:32:12

US3092238

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:21:55
User entered 'I'	System	26 Mar 2021 21:32:12

US3092238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:51:39

US3092238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:51:39

US3092238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Apr 2021 16:51:39

US3092238

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 16:51:39

US3092238

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:51:43

US3092238

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 16:51:43

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:13

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 00:20:15

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:13

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11:00'	Marissa Cervenka (b) (4)	14 Jan 2021 00:20:15

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:13

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '13 Jan 2021 11:00'	System	14 Jan 2021 00:20:15

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:13

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:20:15

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:09:13

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:20:15

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 1 (Day 1)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30
User entered '11 Jan 2020'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:33:21
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Severe (Severe)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:22:02

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 2 (Day 2)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30
User entered '12 Jan 2020'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:33:21
User entered '0'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:23:44

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered missing code ND - Not Done.	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)' reason for change: Data Entry Error	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17
User entered 'Not Done (Not Done)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Severe (Severe)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Severe (Severe)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:23:44

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 3 (Day 3)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30
User entered '13 Jan 2020'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '96'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98.2' F	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Moderate (Moderate)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Severe (Severe)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Severe (Severe)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:17

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered empty.	System	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:05:30

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:06:22

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '16 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:07:48

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '17 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:09:20

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Folder: Covid-19 Assessment 13 Jan 2021

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '99'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '%'	System	23 Jan 2021 00:10:11

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Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Form: Symptom Log (8)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Form: Symptom Log (8)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

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Form: Symptom Log (8)

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Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:09:13

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:10:11

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'Per CDM: Response noted, however please update the results upon availability. Otherwise clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 06:39:56
Query 'Per CDM: Response noted, however please update the results upon availability. Otherwise clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 23:12:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Jan 2021 00:12:56
User opened query 'Per CDM: Response noted, however please update the results upon availability. Otherwise clarify. Thank you.' (Site from DM).		19 Jan 2021 12:43:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Jan 2021 12:41:12
Query 'Data is required. Please complete.' answered with 'PENDING RESULTS' (Site from System).	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:26:13
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Jan 2021 00:25:42
User entered empty.	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User closed query 'The Date of Test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	14 Jan 2021 00:26:03
User entered '13 Jan 2021' reason for change: Data Entry Error	System	14 Jan 2021 00:26:03
User opened query 'The Date of Test is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42
User entered '13 Jan 2020'	System	14 Jan 2021 00:25:42
	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42
	(b) (4)	

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Nasal Swab (Nasal Swab)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 00:25:42

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:09:13

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User entered '0'	System	23 Jan 2021 00:12:56

US3092238

Folder: Covid-19 Assessment 13 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:09:13

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Jan 2021 23:12:21
User entered 'Yes (Y)'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:20:20

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 3 (Day 3)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 5 (Day 5)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 7 (Day 7)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 9 (Day 9)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 14 (Day 14)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 21 (Day 21)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:13

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User accepted default value 'Day 28 (Day 28)'		23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:13

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Jan 2021 00:13:44

US3092238

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:10
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Clinic (Clinic)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:10
User entered 'SICKD1'	System	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11:18'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User entered '13 Jan 2021 11:18'	System	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '164' cm	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53
DataPoint set to visible.	System	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '302.4' lb	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53
DataPoint set to visible.	System	14 Jan 2021 00:28:14

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '98.2' F	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Oral (Oral)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered empty.	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '65'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User entered 'bpm'	System	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '15'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User entered 'breaths/min'	System	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '116'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User entered 'mmHg'	System	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '73'	Marissa Cervenka (b) (4)	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15
User entered 'mmHg'	System	14 Jan 2021 00:29:53

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15

US3092238

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:15

US3092238

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:20
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:30:01

US3092238

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:20
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '13 Jan 2021'	Marissa Cervenka (b) (4)	14 Jan 2021 00:30:01

US3092238

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:09:13

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	14 Jan 2021 00:30:10

US3092238

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:09:13

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:16:24
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
Query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 12:33:16
' canceled (Site from DM).		
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 13 JAN 2021, is still missing in PPD GCL records. Please review if the sample has been shipped, if yes, then please provide the Accession number, Tracking number, shipping date in response, as this helps to track the sample with the details provided. Please also confirm if the site had scan in barcodes through Preclarus, so that the data reflects in PPD GCL records. Thank you.	(b) (4), (b) (6)	29 Jan 2021 09:03:11
' (Site from DM).		
User entered '13 Jan 2021'	Marissa Cervenka (b) (4) (b) (4)	14 Jan 2021 00:30:10

US3092238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:42:54

US3092238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:42:54

US3092238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:42:54

US3092238

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

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'UNBLND_DECIDE'	System	29 Jan 2021 18:42:54

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:06:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:04:29

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:06:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:04:29

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:24:37
User entered 'mRNA-1273 (mRNA-1273)'		29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:24:37
User entered 'mRNA-1273 (mRNA-1273)'		29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:24:37
User entered 'mRNA-1273 (mRNA-1273)'		29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
Signature has been broken.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:05:46
User entered 'Yes (Y)' reason for change: Data Entry Error		01 Mar 2021 20:05:46
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 17:24:45
User entered 'Yes (Y)' reason for change: Data Entry Error		05 Feb 2021 17:24:37
User entered 'No (N)'		29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '1'	System	05 Feb 2021 17:24:37
User entered empty.	System	29 Jan 2021 18:43:10

US3092238

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

Form: Unblinding

Generated On: 09 Jun 2021 15:09:13

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'I'	System	01 Mar 2021 20:05:46
User entered empty.	System	05 Feb 2021 17:24:45
User entered 'I'	System	05 Feb 2021 17:24:37
User entered empty.	System	29 Jan 2021 18:43:10

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '164.0' cm	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '300.6' lb	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '50.80174'	System	01 Mar 2021 20:09:35
DataPoint set to visible.	System	01 Mar 2021 20:05:46

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '164.0' cm	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '300.6' lb	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '50.80174'	System	01 Mar 2021 20:09:35
DataPoint set to visible.	System	01 Mar 2021 20:05:46

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User accepted default value 'Pre-Dose (PREDOSE)'		01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '09:15'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '26 Feb 2021 09:15'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '59'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'bpm'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'breaths/min'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '100'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'mmHg'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '60'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'mmHg'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '164.0' cm	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '300.6' lb	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:09:13

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '50.80174'	System	01 Mar 2021 20:09:35
DataPoint set to visible.	System	01 Mar 2021 20:05:46

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User accepted default value 'Post-Dose (POSTDOSE)'		01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '11:29'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '26 Feb 2021 11:29'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '56'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'bpm'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'breaths/min'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '107'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'mmHg'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '62'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:09:35

US3092238

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'mmHg'	System	01 Mar 2021 20:09:35

US3092238

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:10:15

US3092238

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:10:15

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '26 Feb 2021'	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Urine (URINE)'	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Negative (NEGATIVE)'	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'No (N)'	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	Marissa Cervenka (b) (4)	01 Mar 2021 23:02:04

US3092238

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

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered empty.	System	01 Mar 2021 23:02:04

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'mRNA-1273'	System	01 Mar 2021 20:13:36
DataPoint set to visible.	System	01 Mar 2021 20:05:46

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered '10:57'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '26 Feb 2021 10:57'	System	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'ONCE'	System	01 Mar 2021 20:13:36

US3092238

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

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 20:13:36

US3092238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:21

US3092238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:21

US3092238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11:51'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:21

US3092238

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '29 Jan 2021 11:51'	System	29 Jan 2021 18:44:21

US3092238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:32

US3092238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:32

US3092238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered '11:49'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:44:32

US3092238

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered '29 Jan 2021 11:49'	System	29 Jan 2021 18:44:32

US3092238

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

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User signature succeeded.	Valentine Ebuh (b) (4)	07 Mar 2021 18:31:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:15:08

US3092238

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

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:39:02
User entered 'I'	System	01 Mar 2021 20:15:08

US3092238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:05:48

US3092238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '05 Mar 2021'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:05:48

US3092238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:05:48

US3092238

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:05:48

US3092238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:05:54

US3092238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User entered 'I'	System	09 Mar 2021 01:05:54

US3092238

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:51:12
User entered 'I'	System	09 Mar 2021 01:05:54
DataPoint set to visible.	System	09 Mar 2021 01:05:54

US3092238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:54
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has OL-D29 sample Barcode # 1F653339665 labelled as 26Feb21, however the OL-D29 was performed on 26Mar2021. Please review the Preclarus and confirm the correct date of collection and amend the EDC and Preclarus as appropriate. Thank you.' (Site from DM).		29 Apr 2021 21:28:26
Query 'Per GCL LAB Recon: Immunogenicity: GCL has OL-D29 sample Barcode # 1F653339665 labelled as 26Feb21, however the OL-D29 was performed on 26Mar2021. Please review the Preclarus and confirm the correct date of collection and amend the EDC and Preclarus as appropriate. Thank you.' answered with 'confirmed 1F653339665 labelled as 26Feb21 sample is for OL-1 visit. DCF was submitted to Preclarus on 4/16/21' (Site from DM).	Vicki Martinez (b) (4) (b) (4)	17 Apr 2021 00:48:05
User opened query 'Per GCL LAB Recon: Immunogenicity: GCL has OL-D29 sample Barcode # 1F653339665 labelled as 26Feb21, however the OL-D29 was performed on 26Mar2021. Please review the Preclarus and confirm the correct date of collection and amend the EDC and Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:37:04
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 21:33:23

US3092238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:54
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:23

US3092238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:54
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:33:23

US3092238

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:54
User entered 'OLD29'	System	26 Mar 2021 21:33:23

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User accepted default value 'Pre-Dose (PREDOSE)'		26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '10:25'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered '26 Mar 2021 10:25'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '61'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'bpm'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'breaths/min'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '124'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'mmHg'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '79'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'mmHg'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User accepted default value 'Post-Dose (POSTDOSE)'		26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '11:42'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered '26 Mar 2021 11:42'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '62'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'bpm'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '18'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'breaths/min'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '120'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'mmHg'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '73'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered 'mmHg'	System	26 Mar 2021 21:35:18

US3092238

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:37

US3092238

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:35:37

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:22:08
User entered empty.	System	26 Mar 2021 21:36:10

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 28Mar2021 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 19:58:22
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 28Mar2021 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 added.' (Site from DM).	Catina Adams (b) (4) (b) (4)	08 Apr 2021 15:34:48
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Sample dated 28Mar2021 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 04:37:21
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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 Apr 2021 19:21:46
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User entered 'mRNA-1273'	System	26 Mar 2021 21:36:59
DataPoint set to visible.	System	09 Mar 2021 01:05:54

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User closed query 'Pharmacy source dose worksheet notes subject was dosed on 26Feb2021. Please verify with subject source chart and ensure EDC matches both sections of source for injection date. ' (Site from CRA).		26 Apr 2021 12:26:50
Query 'Pharmacy source dose worksheet notes subject was dosed on 26Feb2021. Please verify with subject source chart and ensure EDC matches both sections of source for injection date. ' answered with 'SUBJECT seen on 26 FEB 2021 for OL-Day1 vaccine. Subject came on 29 JAN 2021 for decision visit but didn't get vaccine. Subject seen on 26 MAR 2021 for OL-Day 29 visit.' (Site from CRA).	Catina Adams (b) (4) (b) (4)	08 Apr 2021 15:32:59
User opened query 'Pharmacy source dose worksheet notes subject was dosed on 26Feb2021. Please verify with subject source chart and ensure EDC matches both sections of source for injection date. ' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 20:24:14
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	28 Mar 2021 01:06:01
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered '11:12'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User entered '26 Mar 2021 11:12'	System	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User entered 'ONCE'	System	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:09:13

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User entered 'INTRAMUSCULAR'	System	26 Mar 2021 21:36:59

US3092238

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User signature succeeded.	Valentine Ebuh (b) (4)	28 Mar 2021 01:06:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 21:37:03

US3092238

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:21:46
User entered 'I'	System	26 Mar 2021 21:37:03

US3092238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:18:49

US3092238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (6)	15 Apr 2021 13:29:01
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
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 'DATA CORRECT' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:18:59
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	07 Apr 2021 22:18:49
User entered '06 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 22:18:49

US3092238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:18:49

US3092238

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:09:13

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:18:49

US3092238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:18:36

US3092238

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:09:13

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 22:18:36

US3092238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:53:32

US3092238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:53:32

US3092238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	30 Apr 2021 16:53:32

US3092238

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:09:13

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Apr 2021 16:53:32

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:05'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 10:05'	System	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.0' F	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '124'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	(b) (4), (b) (6)	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:09:13

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Apr 2021 16:57:26

US3092238

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:58:11

US3092238

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:09:13

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:58:11

US3092238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Apr 2021 16:58:59

US3092238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Apr 2021'	(b) (4), (b) (6)	30 Apr 2021 16:58:59

US3092238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:32'	(b) (4), (b) (6)	30 Apr 2021 16:58:59

US3092238

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Apr 2021 10:32'	System	30 Apr 2021 16:58:59

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:09:13

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:49
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '26 Mar 2021'	Catina Adams (b) (4)	08 Apr 2021 15:33:33

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:09:13

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:49
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '0'	Catina Adams (b) (4)	08 Apr 2021 15:33:33

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:09:13

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:49
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '0'	Catina Adams (b) (4)	08 Apr 2021 15:33:33

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:09:13

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:49
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered 'I'	Catina Adams (b) (4)	08 Apr 2021 15:33:33

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:09:13

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:49
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '0'	Catina Adams (b) (4)	08 Apr 2021 15:33:33

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:57
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered 'Yes (Y)'	Catina Adams (b) (4)	08 Apr 2021 15:34:23

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:57
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '26 Mar 2021'	Catina Adams (b) (4)	08 Apr 2021 15:34:23

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:57
User signature succeeded.	Valentine Ebuh (b) (4)	14 Apr 2021 01:03:40
User entered '11:04'	Catina Adams (b) (4)	08 Apr 2021 15:34:23

US3092238

Folder: Unscheduled 26 Mar 2021

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:09:13

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:27:57
User entered '26 Mar 2021 11:04'	System	08 Apr 2021 15:34:23

US3092238

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:09:13

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:47
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:35:50

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:37:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:37:59
Data point term sent to Coder	System	25 Nov 2020 00:37:12
User entered 'HEADACHE'	(b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '07 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User entered empty.	System	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User entered empty.	System	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User entered '0'	System	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53
User entered '0'	System	25 Nov 2020 00:36:51

US3092238

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 02:23:37
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:08:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Allergic sinusitis, LLT: Seasonal sinusitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:04:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:04:52
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' answered with 'Updated to seasonal.' (Site from DM).	Catina Adams (b) (4) (b) (4)	09 Apr 2021 11:55:45
Data point term sent to Coder	System	09 Apr 2021 11:55:33
Coding entries removed.	Catina Adams (b) (4) (b) (4)	09 Apr 2021 11:55:28
Signature has been broken.	Catina Adams (b) (4) (b) (4)	09 Apr 2021 11:55:28
User entered 'SEASONAL ALLERGIES/SINUSITIS' reason for change: Data Entry Error	Catina Adams (b) (4) (b) (4)	09 Apr 2021 11:55:28
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:59:31
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Mar 2021 22:51:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:21:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Allergic sinusitis, LLT: Allergic sinusitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:39:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:39:43
Data point term sent to Coder	System	09 Mar 2021 01:15:18
Query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term	(b) (4), (b) (6)	09 Mar 2021 01:14:41
' answered with 'CONFIRMED, UPDATE MADE ' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	09 Mar 2021 01:14:25
User entered 'ALLERGIES/SINUSITIS' reason for change: Data Entry Error		09 Mar 2021 01:14:25
User opened query 'Per MM: please confirm if a more specific diagnosis was identified. If yes, please update event term		15 Feb 2021 16:00:27
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 00:38:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Jan 2021 00:38:11
Data point term sent to Coder	System	14 Jan 2021 00:37:24
User entered 'suspected COVID-19'	(b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User entered empty.	System	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:42:52
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:30:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:29:51
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).		20 Mar 2021 07:21:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:29:51
User entered empty.		14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User entered empty.	System	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
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)	23 Mar 2021 03:43:01
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 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:30:13
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 19:29:51
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).		20 Jan 2021 12:45:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Not Related (NOT RELATED)'	(b) (4)	22 Mar 2021 19:29:51
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Not Applicable (NOT APPLICABLE)'		14 Jan 2021 00:36:47

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	31 Mar 2021 16:40:59
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, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:50:11
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, else clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:41:58
Signature has been broken.	(b) (4), (b) (6)	26 Mar 2021 16:41:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error		26 Mar 2021 16:41:50
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, else clarify. ' (Site from DM).		26 Mar 2021 08:53:53
User signature succeeded.		23 Mar 2021 22:51:42
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:29:51
User entered 'Not Applicable (NOT APPLICABLE)'		14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User signature succeeded.	(b) (4)	25 Mar 2021 01:49:56
	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 19:38:16
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Mar 2021 07:21:27
User entered '1'	(b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:29:51
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User entered '0'	System	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59
User entered 'I'	System	14 Jan 2021 00:36:47

US3092238

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:54:59

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:35
User entered 'USA-US086-2021-mRNA-1273-P301000016'	System	29 Apr 2021 19:15:30
User entered 'New'	(b) (4), (b) (6)	29 Apr 2021 19:15:30

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 16:53:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 16:53:56
Data point term sent to Coder	System	29 Apr 2021 15:13:25
User entered 'abdominal pain'	destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered 'Yes (Y)'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'No (N)'	(b) (4) destiny robinson (b) (4) (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered '17 Apr 2021'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered '21 Apr 2021'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 15:14:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 15:14:07
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	29 Apr 2021 15:13:15
User entered 'No (N)'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered '0'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	29 Apr 2021 15:13:15
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	29 Apr 2021 15:13:15
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 15:13:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	29 Apr 2021 14:30:26
User entered '0'	destiny robinson (b) (4) (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '18 Apr 2021'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered '21 Apr 2021'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered 'No (N)'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered empty.	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4) (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'Not Related (NOT RELATED)'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'None (NONE)'	(b) (4) destiny robinson (b) (4) (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered 'I'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
	(b) (4)	
User entered '0'	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

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 22:38:17
	(b) (4)	
User entered empty.	destiny robinson (b) (4)	29 Apr 2021 14:30:26
	(b) (4)	

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'Subject was in the hospital from 4/18/21 to 4/21/21 for abdominal pain that began 4/17/21. She was admitted on 4/18/21 to Charlton Methodist hospital on wheatland Dallas,Tx. Waiting for medical records to give more details.'	(b) (4) destiny robinson (b) (4)	29 Apr 2021 14:30:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 15:14:07
User entered '0'	System	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 14:30:26

US3092238

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:09:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 14:30:26

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:09:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:06:47
User signature succeeded.	Valentine Ebuh (b) (4)	23 Feb 2021 04:10:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:37:04

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Dec 2020 08:43:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 08:43:29
Data point term sent to Coder	System	28 Dec 2020 19:50:36
Coding entries removed.	destiny robinson (b) (4) (b) (4)	28 Dec 2020 19:50:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:43:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:43:58
Data point term sent to Coder	System	25 Nov 2020 00:43:14
User entered 'MIRENA'	(b) (4), (b) (6) (b) (4)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 05:50:06
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'CONFIRMED, UPDATE MADE ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 01:17:26
User entered 'Yes (Y)' reason for change: Data Entry Error		29 Jan 2021 00:22:53
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).		08 Jan 2021 18:35:04
User entered 'No (N)'		25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'CONTRACEPTIVE'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '52'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Q 5 YEARS'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 12:54:49
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. answered with 'EITHER VAGINAL OR UTERUS. PLEASE CLARIFY IF ANSWER IS INCORRECT' (Site from DM).	destiny robinson (b) (4) (b) (4)	28 Dec 2020 19:50:58
User entered 'Other (OTHER)' reason for change: Data Entry Error	destiny robinson (b) (4) (b) (4)	28 Dec 2020 19:50:28
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 02:29:18
User entered 'Vaginal (VAGINAL)'	(b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
	(b) (4)	
User entered 'UTERUS' reason for change: Data Entry Error	destiny robinson (b) (4)	28 Dec 2020 19:50:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 00:42:39

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH PIPERAZINE STRUCTURE, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 04:53:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 04:53:02
Data point term sent to Coder	System	25 Nov 2020 00:44:14
User entered 'COMPAZINE'	(b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'HEADACHE'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '5'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '07 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 05:50:47
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' answered with 'CONFIRMED AND UPDATE MADE ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 01:16:35
User entered 'No (N)' reason for change: Data Entry Error		09 Mar 2021 01:15:55
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol (i.e start date is beyond Day 7 from treatment date). Review and update entry as appropriate.' (Site from DM).		08 Jan 2021 18:36:02
User entered 'Yes (Y)'		25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User entered '1'	System	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User entered '1'	System	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:18
User entered '804 (804)'	System	25 Nov 2020 00:43:41

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:47:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 19:47:49
Data point term sent to Coder	System	22 Mar 2021 19:31:34
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 19:31:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 00:39:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 00:39:17
Data point term sent to Coder	System	14 Jan 2021 00:38:24
User entered 'MUCINEX'	(b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'ALLERGIES/SINUSITIS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:31:11
User entered 'SUSPECTED COVID 19'		14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '600' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:32
User entered '25'		14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '11 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:31:11
User entered 'Yes (Y)'		14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:31:11
User entered empty.		14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User entered empty.	System	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User entered empty.	System	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:22
User entered empty.	System	14 Jan 2021 00:37:45

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 11:55:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 11:55:30
User signature succeeded.	Valentine Ebuh (b) (4) (b) (4)	23 Mar 2021 22:51:42
Data point term sent to Coder	System	22 Mar 2021 19:35:37
Coding entries removed.	(b) (4), (b) (6)	22 Mar 2021 19:34:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 14:44:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 14:44:02
Data point term sent to Coder	System	14 Jan 2021 00:38:25
User entered 'BENADRYL'	(b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'ALLERGIES/SINUSITIS' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:47
User entered 'SUSPECTED COVID 19'		14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '25'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:47
User entered 'Yes (Y)'		14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Mar 2021 19:34:47
User entered empty.		14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User entered empty.	System	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User entered empty.	System	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:09:13

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:27
User entered empty.	System	14 Jan 2021 00:38:22

US3092238

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:09:13

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	23 Mar 2021 22:51:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 01:08:39

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'USA-US086-2021-MRNA-1273-P301000016'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Yes (Y)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Yes (Y)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Valentine'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Ebuh'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered '2701 S Hampton Road, Suite 250'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Dallas'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'TX'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered (b) (6)	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'US'	(b) (4) System	29 Apr 2021 19:15:55

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 19:15:55

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'USA-US086-2021-MRNA-1273-P301000016'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

Serious

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Yes (Y)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Yes (Y)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'No (N)'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Valentine'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Ebuh'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered '2701 S Hampton Road, Suite 250'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'Dallas'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered 'TX'	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:50
User entered (b) (6)	System	29 Apr 2021 19:15:30

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered 'US'	(b) (4) System	29 Apr 2021 19:15:55

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:09:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 19:15:55

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:09:13

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Valentine Ebuh (b) (4)	29 Apr 2021 22:38:17
User entered '29/Apr/2021 12:15'	(b) (4) System	29 Apr 2021 19:15:55

US3092238

Folder: SAE USA-US086-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:09:13

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)	29 Apr 2021 22:38:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:15:55